IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOSEPH C. COLACICCO, Plaintiff,	:	CIVIL ACTION
v.	:	
APOTEX, INC., et al. Defendants.	:	NO. 05-5500

MEMORANDUM

Baylson, J. **May 25, 2006**

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I. Introduction

Presently before this Court are two Motions to Dismiss, pursuant to F.R. Civ. P. 12(b)(6), filed separately by Defendants Apotex, Inc. and Apotex Corp. ("Apotex") and Defendant GlaxoSmithKline ("GSK").

The threshold issue presented by these motions is preemption – whether regulations of a federal agency, promulgated pursuant to a federal statute, and implementing that statute, require the Court to dismiss this pharmaceutical products liability suit based on common law tort principles alleging that inadequate labeling of a prescription drug led to the suicide of Plaintiff's wife.

The answer is "yes" – when Congress passed the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a), the law which gives the Food and Drug Administration ("FDA") control over the regulation of the prescription drug industry, it vested the FDA with authority to regulate the specifics of drug labeling, making important judgments of what is required for safety of the consuming public, what new drugs may appear in the marketplace, and what warnings their instructions and labels must carry. The analysis that follows will reveal many conflicting court decisions on this topic. Fundamentally, a series of Supreme Court decisions point this Court in the direction of deference, and require dismissal of this case. Accordingly, both Defendants' motions to dismiss will be granted.

II. Background

A. Procedural Background

Plaintiff Joseph Colacicco ("Plaintiff") filed his original complaint on October 21, 2005, alleging the suicide death of his wife, Lois, resulted from the Defendant drug manufacturers' failure to warn of the increased risk of suicidal behavior linked to the anti-depressant Paxil

and/or its generic equivalent. On November 22, 2005, Defendant GSK filed its Motion to Dismiss (Doc. No. 5) ("Def. GSK Mem."). Plaintiff filed a Response (Doc. No. 9) on December 20, 2005, and GSK filed a Reply brief (Doc. No. 11) on December 27, 2005. Defendant Apotex filed a Motion to Dismiss (Doc. No. 10) on December 26, 2005 ("Def. Apotex Mem."), to which Plaintiff responded on February 7, 2006 (Doc. No. 19). By letter dated March 2, 2006, this Court asked counsel to answer questions that arose from its review of the briefs to date. All parties responded on March 13, 2006.(See Doc. No. 26 by Plaintiff, Doc. No. 27 by Defendant GSK, and Doc. No. 28, by Apotex) ("Supp. Mem."). Oral argument was held on March 17, 2006, at which Plaintiff's counsel withdrew Count I (breach of express warranty). On March 22, 2006, we again asked counsel by letter to answer additional questions that had surfaced, to which counsel responded on March 27, 2006 (See Doc. No. 33 by Apotex, Doc. No. 34 by GSK, and Doc. No. 38 by Plaintiff) ("2nd Supp. Mem."). Plaintiff filed an Amended Complaint on March 24, 2006 (Doc. No. 32), which asserted in Count III (fraud and violation of consumer protection law against GSK only) what had in the original complaint been plead as two counts against both Defendants - Count III (fraud) and Count X (violation of consumer protection law).[1] Both Defendants GSK and Apotex filed a Response to the Amended Complaint and Supplemental Brief in Support of their Motions to Dismiss, on March 31, 2006 (Doc. Nos. 39 and 40, respectively), and Plaintiff filed a memorandum in opposition to the renewed motions to dismiss on April 6, 2006 (Doc. No. 41). ("3rd Supp. Mem."). Then, due to the novel preemption issues presented in this case, the Court requested that the FDA file an *amicus* brief, which it did on May 10, 2006 (Doc. No. 45). See Brief for United States as *Amicus Curiae* Supporting Defendants,

[1]As Plaintiff's counsel withdrew Count I (breach of express warranty) on the record at the March 17, 2006 oral argument, the Court understands the Amended Complaint to omit that count as well.

Colacicco v. Apotex, Civ. No. 05-5500, Doc. No. 45 (E.D. Pa. May 10, 2006) ("Colacicco Amicus"). Finally, the parties each submitted a response to the *amicus* brief on May 17, 2006 (Docs. No. 48, 49, 50) ("4th Supp. Mem.").

B. Allegations in the Complaint

According to the Complaint, Plaintiff's wife, Lois Ann Colacicco, complained to her oncologist on October 6, 2003 of mild fatigue and depression. She was prescribed Paxil,[2] an anti-depressant drug manufactured by Defendant GSK. Soon thereafter, she began taking the generic version of the drug, paroxetine hydrochloride, which is a bio-equivalent of Paxil and manufactured by Defendant Apotex.[3] On October 28, 2003, after twenty-two days of ingesting the drug, Lois Colacicco committed suicide in her home.

Paxil is one of a class of drugs known as Selective Serotonin Reuptake Inhibitors ("SSRIs"), which are prescribed for the treatment of depression and anxiety. Plaintiff alleges that despite ample peer-reviewed scientific literature published from the mid-1990s onward linking SSRIs to an increased risk of suicidality, at the time of Plaintiff's decedent's death the FDA–approved label did not warn of an association between Paxil (manufactured by GSK) and/or its generic equivalent (manufactured by Apotex) and suicidality.[4]

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[2]The medical records do not indicate whether Lois' physician prescribed Paxil or its generic version; however, it is undisputed that she actually took the generic version.

[3]The FDA approved Apotex's application to produce the generic form of Paxil on June 30, 2003.

[4]The FDA recently retreated from its longstanding position that no linkage existed associating suicidality in adults with SSRI antidepressants, including Paxil. On June 30, 2005, the FDA issued a public health advisory warning of the potential for antidepressant medications to cause suicidal thoughts and behavior in adults. FDA Public Health Advisory, Suicidality in Adults Being Treated with Antidepressant Medications, June 30, 2005, *available at* http://www.fda.gov/cder/drug/advisory/SSRI200507.htm. The FDA is currently engaged in a comprehensive scientific review of existing studies to determine whether there is an increased risk of suicidal behavior in adults treated with antidepressant drugs. Colacicco Amicus at 11. On May 11, 2006, citing the results of a clinical study of nearly 15,000 patients treated with both

Plaintiff filed suit against both Defendants GSK and Apotex, asserting the liability of either or both based on a failure-to-warn theory. Plaintiff contends the warnings, which were disseminated to doctors and the public by GSK, were inadequate to inform adult users of the risk of suicide associated with the drug. He asserts the labeling was prepared solely by Defendant GSK and copied verbatim by Defendant Apotex, which was required as part of the process to obtain approval from the federal FDA to manufacture the generic version of the drug. Alternately, Plaintiff asserts Defendant Apotex manufactured the drug which caused Lois Colacicco's death, and failed to warn adult users of the risk of suicide posed by the drug.

III. Jurisdiction and Legal Standard

A. Jurisdiction

This Court has diversity jurisdiction over this complaint pursuant to 28 U.S.C. § 1332 because the matter in controversy exceeds $75,000 and is between citizens of different states. Plaintiff is a resident of New York. Defendant GSK is a citizen of Pennsylvania. Defendant Apotex is citizen of Florida and Canada.

Venue is appropriate in this district, pursuant to 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to Plaintiff's claims occurred in Pennsylvania or were intended to have consequences in Pennsylvania.

B. Legal Standard

When deciding a motion to dismiss pursuant to F.R. Civ. P. 12(b)(6), the court may grant the motion only if, accepting all well-pleaded allegations in the complaint as true, and viewing

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Paxil and placebos, GlaxoSmithKline warned doctors via a letter that Paxil may raise teen suicide risk. See Associated Press, FDA Warns of Suicide Risk for Paxil, May 12, 2006, *available at* http://hosted.ap.org/dynamic/stories/P/PAXIL_SUICIDE_RISK?SITE=COBOU&SECTION=HOME&TEMPLATE=DEFAULT.

them in the light most favorable to plaintiff, the plaintiff is not entitled to relief. Doug Grant, Inc. v. Greate Bay Casino Corp., 232 F.3d 173, 183 (3d Cir. 2000). Accordingly, a federal court may dismiss a complaint for failure to state a claim only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations. Doe v. Delie, 257 F.3d 309, 313 (3d Cir. 2001).

C. Applicable State Law

As a federal court sitting in diversity, Erie R.R. Co. v. Tompkins, 304 U.S. 64 (1938), requires that we apply the substantive law of the forum state. Id. at 78-80. Pursuant to a joint stipulation of all parties, Pennsylvania is the appropriate forum state, and thus the law of Pennsylvania will be applied to Counts I-II, and IV-IX, as well as the fraud portion of Count III of Plaintiff's Complaint. See Exhibit A, Joint Stip. of the Parties at p. 2 ¶ 1.[5] Count III also asserts a violation of the New York Consumer Protection law, to which New York law applies.

IV. Contentions of the Parties

A. Defendants

Both Defendants GSK and Apotex contend Plaintiff's entire complaint must be dismissed, because (1) it is impliedly preempted by federal law, (2) Defendants do not owe the Plaintiff a duty of care, (3) the learned intermediary doctrine applies, and (4) Hahn v. Richter, 673 A.2d 888, 891 (Pa. 1996), precludes all Plaintiff's claims except those against the seller that sound in negligence.

Speaking to the threshold issue of preemption, Defendants urge that allowing Plaintiff's

[5]Given that Plaintiff's decedent's prescription was prescribed and filled in New York, and she ingested it there, this Court asked counsel by letter dated March 2, 2006 to identify any possible conflict of law issues. The stipulation, which arose as a response to this letter, states that with regard to Counts I through IX, "the law of New York and the law of Pennsylvania are not in conflict, and thus, the laws of Pennsylvania should be applied thereto." Exhibit A, Joint Stip. of the Parties at p. 2.

case to proceed would thwart the purpose of, and thus actually conflict with, the FDCA, and also that this Court must afford deference to the FDA's position that its regulations preempt state tort claims. Regarding a duty of care, GSK decrees that as an innovator drug manufacturer, it does not owe a legal duty to a consumer of the generic equivalent of its drug. Apotex asserts that pursuant to the statute governing FDA approval of generic drugs, it was not responsible for the form or content of the paroxetine hydrochloride labeling, and therefore it too did not owe a duty of care to Plaintiff. Third, Defendants urge that the learned intermediary doctrine applies to bar Plaintiff's complaint because adequacy is a question of law and the FDA's grant of original approval presumptively shows that the warnings were adequate. Finally, Defendants argue that Hahn, which held that "where the adequacy of warnings associated with prescription drugs is at issue, . . . the manufacturer's negligence is the only recognized basis of liability," precludes all Plaintiff's claims except those that sound in negligence. 673 A.2d at 891.

Defendants also advance several arguments for dismissal with regards to Plaintiff's individual causes of action. First, Defendant Apotex contends that a claim for breach of implied warranty (Count II) is not available in cases involving prescription drugs under Pennsylvania law. Next, Defendant GSK argues that Count III (fraud and violation of New York consumer protection statute), which is advanced only against it, fails because: (1) the fraud portion lacks the required particularity under F.R. Civ. P. 9(b), and (2) the consumer protection portion is alleged under the wrong statutory section, does not plead reliance, and is inconsistent with the learned intermediary doctrine. Third, both Defendants assert that Plaintiff's infliction of emotional distress counts (Counts V and VI) fail because the alleged wrongful conduct visited upon his wife did not occur in Plaintiff's presence. Next, Apotex urges Plaintiff's negligence claim (Count VII) must be dismissed because Plaintiff cannot show the existence of a duty and

the negligence *per se* claim (Count VIII) is impliedly preempted. Last, as to the negligent misrepresentation claim (Count IX), Apotex urges that since it made no statements regarding the efficacy and safety of paroxetine hydrochloride to the FDA, Plaintiff cannot show the required element that Apotex knew or should have known that any such representations were false.

B. Plaintiff

Plaintiff argues that preemption is inappropriate for several reasons, including that: (1) the FDCA merely establishes minimum standards and permits manufacturers to unilaterally strengthen warning labels, and (2) deference is unsuitable because the FDA's policy has been inconsistent, and would violate the principle forbidding retroactive application of new rules. Next, Plaintiff urges that pursuant to Pennsylvania's nuanced duty of care analysis, the Court should find that Defendant GSK owed him a duty of care. As to Apotex, Plaintiff asserts that Apotex, like all product manufacturers, cannot escape the duty it owes to its consumers. Further, Plaintiff contends that the learned intermediary doctrine requires an analysis of the adequacy of the warnings, which is a question of fact that cannot be determined at the 12(b)(6) stage. Finally, regarding Hahn, Plaintiff asserts that a broad reading is improper; Hahn is better understood to have a narrower holding.

As to the individual counts, Plaintiff argues his implied warranty claim is viable, attempting to distinguish the case cited by Apotex. He also cites to numerous specific allegations in his complaint supporting the fraud claim, and argues GSK's prolific, deceptive, "direct-to-consumer" advertising sufficiently supports his consumer protection claim. Next, Plaintiff contends that as to the infliction of emotion distress counts, it is sufficient that he observed the *result* of the alleged intentionally outrageous or negligent conduct. Advancing the same arguments as it did earlier, Plaintiff asserts he has shown a duty of care sufficient to

underlie the negligence count, and that preemption is inapplicable to the negligence *per se* claim. Finally, Plaintiff maintains that at the 12(b)(6) stage, the Court must accept his averments that material submitted to the FDA and the labeling itself was intentionally false and misleading.

V. Federal Regulatory Process: Process to Obtain Approval from the FDA to Market and Sell Prescription Drugs

Analysis of the parties' arguments requires some understanding of the process for approval to market and sell generic drugs. The FDCA mandates that drugs are "safe and effective." 21 U.S.C. § 355(a). Therefore, pharmaceutical manufacturers must obtain regulatory approval for prescription drugs prior to marketing them. Id. For drugs that have not been marketed before, the process for approval requires submission of a new drug application ("NDA"). 21 U.S.C. § 355(a)-(i). The NDA must contain proof of the efficacy and safety of the drug, based on extensive laboratory testing. 21 U.S.C. § 355(b). Further, the FDCA requires refusal of any NDA that includes labeling that "is false or misleading in any particular." 21 U.S.C. § 355(d) (grounds for refusing new drug application). The obligation against misbranding drugs continues thereafter. 21 U.S.C. § 331(a), (b), (k). Under the FDCA, a drug is unlawfully misbranded when its labeling is false or misleading, or does not provide adequate directions for use or adequate warnings against any use dangerous to health. Colacicco Amicus at 4; 21 U.S.C. § 352.

Before 1984, generic drug manufacturers were required to submit their own NDA. Foster v. American Home Products, 29 F.3d 165 (4th Cir. 1994) (applying Maryland law); Tri-Bio Labs., Inc. v. United States, 836 F.2d 135, 138-39 (3d Cir. 1987). Because investigations conducted by the innovator companies were considered trade secrets, generic manufacturers were required to perform their own safety and effectiveness studies. This resulted

in additional expenses being passed to consumers, and delay in bringing generic drugs to the market. Id.

The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Amendments ("H-W Amendments") to the FDCA, Pub. L. No. 98-417, 98 Stat. 1585 (codified at 21 U.S.C. § 355(j), 35 U.S.C. §§ 156, 271, 281), relaxed the procedure for obtaining approval from the FDA to market and sell a generic drug, allowing the generic maker to submit an abbreviated NDA ("ANDA"). Id.[6] The ANDA applicant need only certify that the generic manufacturer will produce a bio-equivalent of the brand name drug and that the labeling and warnings of the generic drug are identical to that of the approved innovator drug. 21 U.S.C. § 355(j)(2)(A).

After approval, a manufacturer may "add or strengthen a contraindication, warning, precaution, or adverse reaction" or "delete false, misleading, or unsupported indications for use or claims for effectiveness." 21 C.F.R. § 314.70(c)(6)(iii)(A), (D). However, in its *amicus* brief submitted to the Court in connection with this case, the FDA explained that "a generic drug manufacturer is not permitted to add a warning or caution to the label without prior approval from the FDA." Colacicco Amicus at 17. This is to assure that any changes to the label would not be "false or misleading," and thus misbrand the drug.

VI. Preemption Issues

In their briefs and at oral argument, both Defendants contended that Plaintiff's claims are preempted by the federal FDCA, urging that: (1) Plaintiff's claims are impliedly preempted

[6]The purpose of the H-W Amendments is "to balance the interests of the generic drug manufacturers, who sought to avoid unnecessary testing, against the research investments of the innovator manufacturers, at the same time mindful of the public need for safe commercial drugs." Tri-Bio Labs., 836 F.2d at 139.

under general preemption principles, and (2) the Supreme Court's holding in Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341 (2000) requires that we find preemption. Further, in response to this Court's request that the FDA file a brief on the novel preemption issues presented in this case, the government submitted an *amicus* brief to the Court on May 10, 2006 which also takes the position that Plaintiff's state law claims are barred by implied preemption.

A. Implied Preemption

Pursuant to the Supremacy Clause, any state law conflicting with the exercise of enumerated federal power is preempted. U.S. Const. art. VI, cl. 2. The United States Supreme Court has long recognized that federal preemption of state law can occur in three types of situations: (1) where Congress explicitly preempts state law ("express preemption"), (2) where preemption is implied because Congress has occupied the entire field ("field preemption"), and (3) where preemption is implied because there is an actual conflict between federal and state law ("conflict preemption"). Schneidewind v. ANR Pipeline Co., 485 U.S. 293, 299-300 (1988); Pokorny v. Ford Motor Co., 902 F.2d 1116, 1121-22 (3d Cir. 1990).

Defendants concede that express and field preemption are not implicated, Def. Apotex's Mem. at 9, pursuing only the "conflict" preemption argument. Such a conflict exists where either (1) the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" or (2) it is "impossible for a . . . party to comply with both state and federal law." Geier v. Am. Honda Motor Co., Inc., 529 U.S. 861, 899 (2000); Pokorny, 902 F.2d at 1120; C.E.R. 1988, Inc. v. Aetna Cas. & Sur. Co., 386 F.3d 263, 268 (3d Cir. 2004).

Geier is the most recent in a consistent, long line of cases that articulate the Supreme Court's principles on implied preemption. In that case, an injured motorist and her parents brought a defective design claim against an automobile manufacturer based on a lack of an

automobile airbag in their 1987 Honda Accord. Geier, 529 U.S. at 865. After concluding that the National Traffic and Motor Vehicle Safety Act of 1966 did not expressly preempt petitioners' claims, the Court held that the claims nonetheless actually conflicted with the objectives of Federal Motor Vehicle Safety Standard 208 ("Standard 208") which gave automobile manufacturers a range of choices among different passive restraint devices which were to be gradually introduced over time. The Court reasoned that plaintiff's claims depended upon the manufacturer having a duty to install an airbag in all 1987 vehicles, which presented an obstacle to the variety and mix of devices that Standard 208 sought. Id. at 881. Therefore, because the Supremacy Clause "forbids conflicts that make it impossible for private parties to comply with both state and federal law," the Court concluded that plaintiff's claims were impliedly preempted. Id. at 873, 875, 886.

Despite the generality of the definition of conflict preemption, the Supreme Court has urged caution in its application: "[B]ecause the States are independent sovereigns in our federal system, we have long presumed that Congress does not cavalierly preempt state-law causes of action." C.E.R. 1988, 386 F.3d at 269-70 (quoting Medtronic Inc. v. Lohr, 518 U.S. 470, 485 (1996) (case involving express preemption). Thus, conflict preemption will be found only if the need for it is clear. Pokorny, 902 F.2d at 1122. In fact, "consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." Bldg. & Constr. Trades Council of Metro. Dist. v. Assoc. Builders & Contractors of Mass./R.I., Inc., 507 U.S. 218, 224 (1993).

In contending that Plaintiff's claims are impliedly preempted by federal law, Defendants principally assert that assigning state tort liability would thwart the purpose of—and thus

actually conflict with—the Hatch-Waxman Amendments.[7] Further, Defendants argue that under clearly established caselaw, this Court must afford deference to the FDA's position that its regulations preempt state tort claims for inadequate warnings, which it has articulated in several *amicus* briefs and in the preamble to new drug labeling regulations issued in 2006. See Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-97 (Jan. 24, 2006) (effective date June 30, 2006) (to be codified at 21 C.F.R. pts. 201, 314, 601) (hereinafter, "Preemption Preamble" to the "Final Rule") (Def. Apotex Mem. at 9-15; Def. GSK Mem. at 9; Apotex Supp. Mem. at 18-24; GSK Supp. at 10-18; Apotex 2nd Supp. Mem. at 2-10; GSK 2nd Supp. Mem. 1-5).

In its *amicus* brief to this Court, the FDA goes even further, asserting that because prior to October 2003, the agency had repeatedly determined that there was inadequate evidence of an association between adult use of SSRIs and suicidality, Plaintiffs' state law failure-to-warn claims are preempted because such a warning statement would actually have been "false and misleading," and thus contrary to federal law. Colacicco Amicus, at 1. We address these arguments in turn.

1. Deference to the FDA's Position that Plaintiff's Claims are Preempted

The Defendants and the FDA point to several pieces of evidence which reflect the FDA's position that Plaintiff's inadequate warning claims are preempted: (1) the May 10, 2006 *amicus* brief filed in this case representing that the FDA would consider such a warning false and misleading (as well as two prior *amicus* briefs filed in other cases by the FDA in 2005 and 2002, respectively, indicating the same), (2) the 2006 Preemption Preamble, an official agency statement purporting to establish preemption of conflicting state law claims.

[7]See *supra* Part V for an in depth discussion of the Hatch-Waxman Amendments.

The FDA's view is critical to this Court's analysis because Supreme Court precedent dictates that an agency's interpretation of the statute and regulations it administers is entitled to deference. Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 844 (1984) (holding that it has been "long recognized that considerable weight should be accorded to an executive department's construction of a statutory scheme it is entrusted to administer"). See also Thomas Jefferson Univ. Hosp. v. Shalala, 512 U.S. 504, 512 (1994); NVE Inc. v. Dept. of Health & Human Servs., 436 F.3d 182, 186 (3d Cir. 2006); C.E.R. 1988, 386 F.3d at 271 n.11. However, deference is not absolute; in deciding whether to afford it, courts should review *inter alia* the consistency with which the agency has applied the particular interpretation. NLRB v. N.J. Bell Tel. Co., 936 F.2d 144, 147 (3d Cir. 1991) (citing West v. Bowen, 879 F.2d 1122, 1134 (3d Cir. 1989)).

In the context of preemption specifically, the Supreme Court held in 1985 that in the absence of clearly expressed Congressional intent or subsequent developments that reveal a change in that position, the FDA's position on the preemptive scope of its regulatory authority "is dispositive." Hillsborough County v. Automated Med. Labs. Inc., 471 U.S. 707, 714 (1985).

Further, the Court has made clear that such preemptive intent may properly be communicated in *amicus* briefs, Geier, 529 U.S. at 883, as well as in "regulations, preambles, interpretive statements and responses to comments." Hillsborough County, 471 U.S. at 718. In recent years, each time the Supreme Court has confronted the question of whether the FDCA preempts state law, it has deferred to the FDA's preemption position.[8] See Geier, 529 U.S. at 883 (noting that the Court "place[s] some weight upon [the federal agency's interpretation of the

[8]For a history of how the Supreme Court has responded to the FDA's position on preemption, see Eric G. Lasker, How Will FDA's New Label Rule Impact Drug Litigation?, 9 No. 10 Andrews Drug Recall Litig. Rep. 9, at 2 (Mar. 13, 2006).

regulation's] objectives and its conclusion . . . that a tort suit . . . would stand as an obstacle to the accomplishment and execution of those objectives"); Medtronic, 518 U.S. at 496 (holding that state law claims involving FDCA section 510(k) medical devices, which are subjected to a relatively cursory approval process, were not preempted because the FDA had taken the position that its regulations only preempted claims involving section 360e(c) devises, which go through a rigorous pre-market approval process); Buckman, 531 U.S. at 353 (in which the Court's holding that the FDCA, as amended by the Medical Devices Amendment ("MDA"), impliedly preempted patients' state law "fraud-on-the-agency" claims mirrored the position taken by the FDA in its *amicus* brief submitted to the court[9]).

The Third Circuit has not rendered an opinion as to the level of deference that should be afforded to the FDA's position on whether the FDCA impliedly preempts state failure-to-warn claims. However, the Third Circuit considered whether to defer to the FDA's position on express preemption in the 2004 case Horn v. Thoratec Corp., 376 F.3d 163, 171 (3d Cir. 2004). Horn held that the plaintiff's state law claims against a heart valve manufacturer were preempted by the express preemption provision of the MDA. Id. at 180. In coming to this conclusion, the court stated that the Supreme Court's decision in Medtronic required it to afford deference to the FDA's position that the claims were preempted. Id. at 179. Moreover, it held that this was the case even though this stance was a change from the FDA's prior position. Id. (noting "we cannot agree [with Plaintiff] that the FDA's position is entitled to no deference or 'near indifference' simply because it represents a departure from its prior position."). The court noted that the Supreme Court in Chevron held that a "revised interpretation by an agency is [still] entitled to deference because an initial agency interpretation is not instantly carved in stone," Id.

[9]See Brief for United States as *Amicus Curiae*, Buckman Co. v. Plaintiffs' Legal Comm., Civ. No. 98-1768, 531 U.S. 341 (2000) (available at 2000 WL 1364441).

(citing Chevron, 467 U.S. at 863-64), and that an agency may change its position "so long as it can justify its change with reasoned analysis." Id. (citing Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto Ins. Co., 463 U.S. 29, 42 (1983)). Horn held that it was "fully persuaded" that the FDA adequately justified its change in position on preemption. Id. Importantly, while the facts of Horn involved the express preemption provision of the MDA, to which there is no corollary part in the prescription labeling provisions of the FDCA, the Horn court broadly announced a policy of affording deference to the FDA's position on preemption, and did not narrow the holding only to cases involving express preemption.

a. The Government's Amicus Briefs

In the *amicus* brief submitted to this Court, the FDA re-affirmed its view that Plaintiff's claims are preempted. Colacicco Amicus at 1, 13, 15. Explaining this position, the FDA noted that the FDCA prohibits the misbranding of drugs. 21 U.S.C. § 331(a), (b), (k). As explained above, under the FDCA, a drug is unlawfully misbranded when its labeling is false or misleading, or does not provide adequate directions for use or adequate warnings against any use dangerous to health. Colacicco Amicus at 4. Therefore, to the extent that before and up to October 2003,[10] the date of Plaintiff's decedent's death, the FDA specifically and repeatedly rejected claims that adult use of SSRI's was associated with increased suicidality because there

[10]The brief, accompanied by a lengthy appendix, outlines how on no less than six occasions between July 1991 and October 2003, the FDA rejected proposals seeking changes in drug labeling regarding suicide for SSRIs. In briefs responding to the Colacicco Amicus, Defendants argued that the Court may consider this information without converting the 12(b)(6) into a motion for summary judgment. (Def. Apotex 4th Supp. Mem at 3-8; Def. GSK 4th Supp. Mem at 5-8). Although the information about the FDA rejecting proposals seeking changes in drug labeling is evidence outside the record, a court may properly take judicial notice of public records and consider them in a 12(b)(6) motion. Pension Benefit Guaranty Corp. v. White Consol. Indus. Inc., 998 F.2d 1192, 1197 (3d Cir. 1993). However, *how* the FDA came to its conclusion is far less relevant than the fact that the FDA *did* conclude Plaintiff's claims are preempted. It is the latter to which we give deference, and therefore these extra-record factual allegations are not determinative to our conclusion.

was no reasonable evidence to support the linkage, the FDA contends that any such warning would have been false or misleading, and contrary to the public interest. For this reason, the FDA asserts that Plaintiff Colacicco's failure-to-warn claims are preempted by federal law. Id. at 17.

Moreover, the FDA explained that public policy requires that warnings be scientifically substantiated. Dissemination of unsupported warnings, the FDA urged, would deprive patients of efficacious treatment, thereby chilling the drug's otherwise beneficial use. Id. at 13. The FDA also flatly rejected the often-cited proposition by many courts refusing to apply preemption in prescription drug cases that 21 C.F.R. § 314.70(c) permits drug makers to unilaterally strengthen a warning label without FDA approval. Id. at 6, 17. Instead, it decreed that despite what numerous lower courts[11] around the nation have stated, a "*drug manufacturer is not permitted to add a warning or caution to the label without prior approval from the FDA*." Id. at 17 (emphasis added).

This position is consistent with the view taken in two prior *amicus* briefs prepared by the FDA in other failure-to-warn cases. See Brief for United States as *Amicus Curiae* Supporting Defendant, Kallas v. Pfizer, Inc., Civ. No. 2:04-cv-0998, 34, 37-38 (D. Utah Sept. 15, 2005) (FDA amicus brief arguing that plaintiff's failure-to-warn claims were preempted because the FDA lacked reasonable evidence of an association between SSRIs and suicidality in children in November 2002; thus, the proposed warning would have misbranded Zoloft, the SSRI at issue) ("Kallas Amicus"); Brief for United States as *Amicus Curiae* Supporting Defendant, Motus v.

[11] See, e.g., McNellis v. Pfizer, Inc., Civ. No. 05-1286, 14 (D.N.J. Dec. 29, 2005); Witczak v. Pfizer, 377 F. Supp. 2d 726, 729 (D. Minn. 2005); Zikis v. Pfizer, Inc., Civ. No. 04-8104, 6 (N.D. Ill. May 9, 2005); Cartwright v. Pfizer, 369 F. Supp. 2d 876, 882 (E.D. Tex. 2005). These case are discussed below at pages 32-34. However, neither the Supreme Court nor the Third Circuit has spoken on this issue.

Pfizer, Inc., Civ. Nos. 02-cv-55372, 02-cv-55498, (9th Cir. Sept. 10, 2002), 2002 WL 32303084, at *16 (amicus brief submitted by FDA contending plaintiff's failure-to-warn case was preempted because, before plaintiff's decedent's death in 1998, the FDA had considered, and rejected, claims that SSRIs were linked to suicidal behavior in adults, and any warning label would have been "false or misleading" and would therefore have misbranded Zoloft, the SSRI at issue) ("Motus Amicus").[12] See also Lori J. Parker, Proof of Injury Resulting from Antidepressant Medication, 87 Am. Jur. Proof of Facts 3d 119, § 3 (2006).

According to the FDA, therefore, it is clear that any insert in October 2003 associating use of paroxetine hydrochloride with suicidality would have constituted misbranding, because it was contrary to the scientific evidence, and thus "false and misleading." Pursuant to the principles announced in the Supreme Court's decisions in Chevron, Medtronic, Geier and their progeny, as well as the Third Circuit's broad holding in Horn, it is therefore appropriate to afford deference to the FDA's position based on the Colacicco Amicus alone.

However, in his response to the Colacicco Amicus, Plaintiff argues that we ought not pay the *amicus* any deference because (1) the FDA glosses over the importance of 21 C.F.R. § 314.70, which it argues allows manufacturers to strengthen labels without prior FDA approval - and which almost every court that has heretofore rejected preemption has cited, and (2) the FDA has no authority to simply declare that a drug is misbranded, and, at any rate, such opinion is

[12]Notably, while the FDA filed *amicus* briefs in both cases, neither Kallas nor Motus resulted in a judicial decision as to preemption. The Kallas case settled before the District of Utah rendered a decision. Kallas v. Pfizer, Inc., Civ. No. 2:04-cv-0998 (D. Utah Oct. 24, 2005) (order granting stipulated motion to dismiss pursuant to settlement). In Motus, while the Ninth Circuit rendered a decision affirming summary judgment in favor of defendant, it did so based on lack of causation, declining to reach the issue of preemption. Motus v. Pfizer, Inc., 358 F.3d 659, 660 (9th Cir. 2004) (because plaintiff failed to establish a sufficient causal link between her husband's suicide and the drug manufacturer's conduct, "we need not reach the preemption issues raised by [defendant]").

merely hypothetical, as at no time prior to Plaintiff's decedent's death did either Defendant request a stronger warning. (Pl.'s 4th Supp. Mem. at 3 n.3, 5, 8-10).

We disagree. As to the Plaintiff's first objection, Plaintiff notes that the plain language of § 314.70 states that the holder of an approved application may make changes in the labeling to "add or strengthen a contraindication, warning, precaution, or adverse reaction," and may "*commence distribution of the drug product involved upon receipt by the agency* of a supplement for the change." 21 C.F.R. § 314.70(c)(6)(iii)(A). He thus contends the provision's plain language explicitly permits manufacturers to strengthen labels *without* prior FDA approval. (Pl.'s 4th Supp. Mem. at 3 n.3). However, 21 C.F.R. § 314.150, cited by the FDA in its *amicus* brief and by Defendant Apotex, directly supports the FDA's position that generic drug makers *can not* unilaterally strengthen their drug. 21 C.F.R. § 314.150 states that the FDA will withdraw approval of a generic maker's ANDA if the label ceases to be identical to that of the name-brand drug. Interpreting § 314.150, the FDA explained, "[i]f an ANDA applicant believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised. After approval of an ANDA, if an ANDA holder believes that new safety information should be added, it should provide adequate supporting information to FDA, and FDA will determine whether the labeling for the generic and listed drugs should be revised." 57 Fed. Reg. at 17961. Moreover, despite the plain language of § 314.70, and even if the FDA's position were not bolstered by 21 C.F.R. § 314.150, this Court believes that principles of deference do not allow us to question the FDA's interpretation of its own regulations – e.g. that generic drug manufacturers can not make changes without prior approval.

As to the second assertion, Plaintiff argues that the FDA must prosecute an enforcement

action to establish a drug is misbranded, citing 21 U.S.C. §§ 331-37, 352. However, these sections merely discuss the requirements of an enforcement or injunctive action if one is brought; no where does the statute declare that the FDA must bring a prosecution to state an *opinion* as to whether a particular drug would have been misbranded if a certain warning had been attached. Further, it is not in dispute that the FDA's position is a hypothetical. In fact, it is in part *because* neither Defendant requested a stronger warning that the vacuum of information was created that necessitated this Court asking the FDA to render an opinion as to preemption. Moreover, we note that the Supreme Court has explicitly stated that *amicus* briefs are an appropriate form to express preemptive intent, Geier, 529 U.S. at 883, which, pursuant to Chevron, Medtronic, Geier, we must afford significant deference.[13]

b. The Preemption Preamble

However, we need not base our conclusion on the *amicus* briefs alone. In early 2006, the FDA additionally promulgated what we refer to as the "Preemption Preamble," which states that, "whether it be in the old or new format, [the FDCA] preempts conflicting or contrary state law," and "conflicting" includes state failure-to-warn claims. 71 Fed. Reg. at 3934, 3936. As in its Colacicco Amicus brief, the FDA in the Preemption Preamble specifically rejected the two main

[13]Plaintiff also argues Sprietsma v. Mercury Marine, 537 U.S. 51 (2002) requires that this Court reject the FDA's position. In Sprietsma, the Supreme Court held the Federal Boat Safety Act (FBSA) did not impliedly preempt plaintiff's common law tort claims, arising out of the defendant manufacturer's failure to install propeller guards on a boat engine. Id. at 64-68. This case, however, is easily distinguishable. First, in Sprietsma, the Coast Guard *declined* to regulate boat propellers completely; they decided to "take no regulatory action." Id. at 65. Here, the FDA's mandate is to affirmatively regulate the approval and labeling of prescription drugs. Second, Sprietsma in part depended on the fact that states were free to adopt their own regulation to regulate propellers. This of course is not so with prescription labeling under the FDCA, where any state law effort to brand a drug different from that approved by the FDA would result in misbranding. Finally, Sprietsma discusses - and distinguishes - Geier, noting that the Coast Guard stated it did *not* view its regulatory actions as having preemptive effect, in obvious contrast to our facts. In sum, Spreitsma is inapposite to the case at hand.

arguments advanced by those courts rejecting preemption: (1) that the FDCA imposes only minimum standards for labeling, and (2) drug manufacturers have the ability to strengthen warnings without FDA approval. 71 Fed. Reg at 3934-35; see also Eric G. Lasker, How Will FDA's New Label Rule Impact Drug Litigation?, 9 No. 10 Andrews Drug Recall Litig. Rep. 9, at 2 (Mar. 13, 2006). As to the "misunderstanding" that FDA labeling requirements represent a minium safety standard, the FDA Preemption Preamble interprets the FDCA to "establish both a 'floor' and a 'ceiling.'" Id. Regarding the argument that manufacturers can modify labels without FDA approval, the FDA urges that "in practice, manufacturers typically consult with FDA before doing so to avoid implementing labeling changes with which the agency ultimately might disagree." Id. Also, as in the Colacicco Amicus brief, the Preamble asserts that "state-law attempts to impose additional warnings can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products." Id.

As discussed above, it is abundantly clear that the FDA's position is entitled to significant deference. Geier, 529 U.S. at 883; Chevron, 467 U.S. at 844; Hillsborough County, 471 U.S. at 714; Horn, 376 F.3d at 180. However, notwithstanding the unambiguous position taken by the FDA in the Colacicco Amicus and in the Preemption Preamble, and despite the general rule requiring deference, Plaintiff argues that deference is not appropriate in this case for three reasons: (1) the preamble is mere legal argument that deserves no weight, (2) the FDA's policy has been inconsistent, and (3) it would be improper to retroactively apply the Preamble.

c. Weight Afforded to FDA's Position

First, Plaintiff argues that the Preemption Preamble amounts to mere legal argument that should not affect this court's inquiry. (Pl.'s Supp. Mem. at 7-11). We disagree. In this case, "the

subject matter [of the FDCA] is technical; and the relevant history and background are complex and extensive," and we find that the FDA is "uniquely qualified to comprehend the likely impact of state requirements." Geier, 529 U.S. at 883, citing Medtronic, 518 U.S. at 496. Given the overwhelming caselaw on the issue of deference, and specifically the Supreme Court's holdings in Geier and Hillsborough County that preemptive intent may properly be communicated in *amicus* briefs, preambles and interpretive statements, we find Plaintiff's argument lacks merit. Geier, 529 U.S. at 883; Hillborough County, 471 U.S. at 718. Further, it is not the function of this Court, or for a jury empaneled to decide this case, to substitute its judgment for the FDA's about these medical issues. Congress has given the FDA broad power, the President has appointed its executives, some subject to the advice and consent of the Senate, and it has rendered its judgment on these issues. The FDA has acted within its authority, and this Court must respect its expert judgment that an October 2003 warning label other than approved by the FDA would have been in direct, actual conflict with federal law.

d. Inconsistency of the FDA's Position

Second, Plaintiff argues that despite the FDA's statements that the Preemption Preamble "represents the government's long standing views" on preemption, 71 Fed. Reg at 3934, and that its argument in the Colacicco Amicus that its position on "federal preemption of . . . failure-to-warn claims [does not] constitute a wholesale change in agency position," in fact, the FDA has not been consistent in its position on preemption. Plaintiff points to two past statements made by the FDA demonstrating that it did not always consider its regulations to have preemptive effect. See 65 Fed. Reg. 81082, 81103 (Dec. 22, 2000) (FDA taking stance in initial proposed version of preamble to what was ultimately enacted as the Final Rule that its regulations are minimum standards, and *do not preempt state tort claims*); 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998)

("[F]ederal preemption could unduly interfere with the goals and objectives of existing State programs . . . This final rule is intended to complement these State efforts, not replace or hinder them."). (Pl.'s Supp. Mem. at 7-11).

In its response to the *amicus* brief, GSK offered some compelling reasons why the 1998 statement ought not be considered inconsistent with the FDA's current position. GSK points out that the 1998 declaration related to the FDA's final regulation on Patient Medication Guides, which is information provided directly to patients, usually by pharmacists. Drug stores and pharmacies, in turn, have traditionally been regulated by the States, not the FDA. See, e.g., 49 Pa. Code § 27.19 (State Board of Pharmacy's regulation concerning prospective drug review and patient counseling). Thus, to the extent that the FDA commented that federal preemption could unduly interfere with state programs, it appears this concerned state programs regarding what information pharmacists must provide *directly to patients*. Because the protections afforded by some of these state programs exceeded that required by federal law, the FDA commented that it did not intend to displace these programs. 63 Fed. Reg. at 66384. Accordingly, we concur with GSK that the 1998 statement does not undermine the FDA's current position on preemption, which concerns what information must be provided *to physicians* about prescription drugs, the regulation of which unquestioningly is exclusively a federal function.

The inconsistency in the December 2000 declaration is more problematic. We find it is difficult to reconcile the FDA's current position with that statement, which was made in the FDA's initial notice of its intent to revise the prescription drug labeling regulations, which ultimately was enacted as the Final Rule. At that time, the FDA "determined that this proposed rule does not contain policies that have federalism implications or that preempt State law." 65 Fed. Reg. at 81103 (emphasis added). Further, despite our specifically asking the FDA to

address whether their current position can be reconciled with the December 2000 statement, the Colacicco Amicus brief is completely silent on the 2000 statement. See Letter to Counsel for the Government Re: Follow-Up Questions for the Amicus Brief, Colacicco v. Apotex, Civ No. 05-5500 (Doc. No. 44) (E.D. Pa. May 4, 2006); Colacicco Amicus at 20.[14] Nonetheless, although consistency of an administrative agency's position is a factor, as Chevron made clear, there is no longer any justification for not giving deference to an agency's interpretation of law merely because it is not the agency's longstanding position. Chevron, 467 U.S. at 863-64 (holding "[t]he fact that the agency has from time to time changed its interpretation . . . does not . . . lead us to conclude that no deference should be accorded the agency's interpretation of the statute. An initial agency interpretation is not instantly carved in stone." See also Horn, 376 F.3d at 179 ("[W]e cannot agree [with Plaintiff] that the FDA's position is entitled to no deference . . . simply because it represents a departure from its prior position.").[15] "On the contrary, the agency, to engage in informed rulemaking, must consider varying interpretations and the wisdom of its policy on a continuing basis." Chevron, 467 U.S. at 863-64; see also Antonin

[14]In their brief responding to the Colacicco Amicus, Defendant GSK tries to argue that the 2000 statement is not inconsistent, because it was made pursuant to Exec. Order No. 13132, 64 Fed. Reg. 43255 (Aug. 4, 1999), which itself does not mention tort liability. Order 13132, GSK asserts, merely requires agencies to state whether its policies have "federalism implications," defined as federal actions that "have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government." 65 Fed. Reg. at 81103. GSK therefore contends that because the definition does not mention private tort suits, it was proper for the FDA to find there were no "federalism implications" of its proposed rule. GSK's argument misses the mark. Certainly to the extent that the FDCA labeling regulations preempt state tort law, this would have "federalism implications," in that a policy stating that federal law completely trumps state failure-to-warn claims axiomatically has a "substantial [effect] . . . on the relationship between the national government and the States."

[15]As discussed *supra*, we recognize that Horn dealt with *express* preemption under the Medical Device Amendments ("MDA") to the FDCA, which unlike the prescription drug labeling portions of the FDCA, contained an express preemption provision. However, as the Third Circuit's holdings were broadly stated, we do not believe this affects the amount of deference a district court must afford the FDA's position on preemption.

Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 Duke L.J. 511, 518 (1989) (Chevron embraces concept that merely because agency interpretation is "new or "changing," it is not somehow suspect).

Moreover, we do find it significant that after 2000, the FDA has been very consistent.[16] On four occasions — in the Colacicco Amicus, the Preemption Preamble, the Kallas Amicus, and the Motus Amicus — it set forth detailed analyses of its position that the Supremacy Clause bars state tort liability specifically for failure to include a warning on a drug label that is in conflict with or contrary to the warnings approved by the FDA. See Colacicco Amicus, Preemption Preamble, Kallas Amicus, Motus Amicus. Moreover, the 1998 and 2000 statements in the Federal Register referred more generally to the regulations and not to the specific circumstances here – where Plaintiff's proposed warning would have misbranded the drug. Dusek v. Pfizer, Inc., No. Civ.A. H-02-3559, 2004 WL 2191804, *6 (S.D. Tex. Feb. 20, 2004) (holding state failure-to-warn claims were preempted, because any warning label linking said drugs to suicide would have been false and misleading). Accordingly, even though the FDA's prior position on preemption has not been entirely consistent, this Court finds it proper to give significant weight to the FDA's unambiguous statement in the Colacicco Amicus brief and in the Preemption Preamble that Plaintiff's claims are preempted. Hillsborough County, 471 U.S. at 714; Chevron, 467 U.S. at 844; Horn, 376 F.3d at 179. See also Needleman v. Pfizer, Inc., 03-CV-3074, 2004 WL 1773697, *2-5 (N.D. Tex. Aug. 6, 2004); Dusek, 2004 WL 2191804 at *10. Accordingly, based on deference alone, this Court would deem any state failure-to-warn claim impliedly preempted.

e. Retroactivity of the Preamble

[16]Further, we find it irrelevant whether the FDA's change in position since 2000 has been because of medical judgments, change in governance, or something else.

Finally, Plaintiff questions whether the Preemption Preamble, promulgated in 2006, may be retroactively applied to the October 2003 death of the decedent in this case. This appears to be an issue of first impression, as only two courts have had occasion to mention the Final Rule, and neither have specifically considered the question of retroactivity as to the Preemption Preamble in particular. Abramowitz v. Cephalon, Inc., 2006 WL 560639, *5 (N.J. Super. Mar. 3, 2006); Laisure-Radke v. Par Pharm., Civ. No. 03-3654, 2006 WL 901657, *3 (W.D. Wash. Mar. 29, 2006).

A brief primer on administrative law is necessary to address the parties' claims because the law governing administrative rule-making, and in turn retroactivity, largely hinges on how the agency's stance is classified – that is, whether the agency's position is a substantive rule, an adjudicative rule, an interpretive rule, or a statement of policy under the Administrative Procedure Act ("APA").

The APA defines a "substantive" or "legislative" rule as "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency" 5 U.S.C. § 551(4). These rules have the force and effect of law and must be promulgated in accordance with the proper notice and comment procedures under the APA. Beazer E., Inc. v. U.S. Envtl. Prot. Agency, Region III, 963 F.2d 603, 606 (3d Cir. 1992). "Interpretive" rules, on the other hand, seek only to interpret the meaning already in properly issued regulations and are meant "to give guidance to its staff and affected parties as to how the agency intends to administer a statute or regulation." Id.; Daughters of Miriam Ctr. for the Aged v. Mathews, 590 F.2d 1250, 1258 (3d Cir. 1978). Thus, "if the rule in question merely clarifies or explains existing law or regulations, it will be deemed interpretive." Bailey v. Sullivan, 885 F.2d 52, 62 (3d Cir. 1989). Further,

interpretive rules and statements of policy are exempted from the APA's notice and comment requirement. Beazer, 963 F.2d at 606.

Similarly excluded from the APA's notice and comment requirements, and lacking the force of law, are "general statements of policy." United States v. Mead Corp., 121 S. Ct. 2164, 2173-75 (2001); Madison v. Res. for Human Dev., Inc., 233 F.3d 175, 179 (3d Cir. 2000). Although the term is not defined in the APA, the Supreme Court has afforded deference to the definition proffered in the Attorney General's 1947 Manual on the Administrative Procedure Act ("Attorney General's Manual"), stating it is a pronouncement "issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." Lincoln v. Vigil, 508 U.S. 182, 197 (1993); Attorney General's Manual 30, n.3 (1947).

The Supreme Court has made clear that substantive rules may not be retroactively applied. Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1998).[17] Here, while the rule to which the Preemption Preamble is attached is the type of rule governed by Georgetown University, the preamble lacks force of law, and is not a substantive rule. However, it is not initially clear whether the Preemption Preamble is an "interpretive rule" or a "statement of policy."

In Appalachian States Low-Level Radioactive Waste Commission v. O'Leary, 93 F.3d 103, 113 (3d Cir. 1996), the Third Circuit held that because an interpretive rule merely clarifies what existing rights and obligations had always been, retroactivity concerns are irrelevant.

[17]Equally clear is the retroactivity of pronouncements announced by adjudication, where an administrative agency issues a regulation through an adversary proceeding, based on the facts and the parties before it. Unlike the case of substantive rule-making, the outcome in adjudication is often — and permissibly — applied retroactively to the parties in the case at hand, so long as this will not result in "manifest injustice." Bowen, 488 U.S. at 219-20 (Scalia, J., concurring). However, as the FDA's preemption policy was not announced via adjudication in the instant case, the retroactivity rules for adjudications are inapplicable.

Accord: United States v. Tomasino, 206 F.3d 739 (7th Cir. 2000); Cowen v. Bank United of Tex., FSB, 70 F.3d 937, 943 (7th Cir. 1995); Pope v. Shalala, 998 F.2d 473, 483 (7th Cir. 1993); Ill. by the Ill. Dep't of Pub. Aid v. Bowen, 786 F.2d 288, 292 (7th Cir. 1986). Cf. Beazer, 963 F.2d at 609 (in case involving the retroactive application of the EPA's interpretation of certain regulatory language via adjudication, which the Third Circuit held to be proper, stating in *dicta* that the "[APA] . . . expressly prohibit[s] an agency from retroactively imposing an interpretive rule upon a regulated party").

However, if the Preemption Preamble is a statement of policy, the law on retroactivity is less clear, particularly in the Third Circuit. While most circuits adhere to the definition of policy statements as pronouncements to "advise the public *prospectively*," Mada-Luna v. Fitzpatrick, 813 F.2d 1006, 1014 (9th Cir. 1987); Am. Hosp. Ass'n v. Bowen, 834 F.2d 1037, 1046 (D.C. Cir. 1987); Burroughs Wellcome Co. v. Schweiker, 649 F.2d 221, 224 (4th Cir. 1981); Am. Bus. Ass'n v. United States, 627 F.2d 525, 529 (D.C. Cir. 1980), the Eleventh Circuit has explicitly held that a statement of policy that clarifies existing law may be applied retroactively. Jean v. Nelson, 711 F.2d 1455, 1479 (11th Cir. 1983). While the Third Circuit has not addressed this issue, we conclude that it would follow the definition in the Attorney General's Manual, which has been afforded deference by the Supreme Court and which states that policy statements only apply *prospectively*, as well as the strong weight of authority that favors the view that policy statements may not be applied retroactively. Lincoln, 508 U.S. at 197; Attorney General's Manual 30, n.3.

Thus, having determined that in the Third Circuit, an "interpretive rule" likely may apply retroactively, but a "statement of policy" likely may not, our determination as to which category the Preemption Preamble falls into is important. Certainly to say that the law in this area is less

than clear is an understatement. See Cmty. Nutrition Inst. v. Young, 818 F.2d 943, 946 (D.C. Cir. 1987) (quoting authorities describing the distinction between legislative rules and general policy statements as "tenuous," "blurred," "baffling," and "enshrouded in considerable smog"). See also Am. Bus. Ass'n, 627 F.2d at 529 (distinction between categories of agency pronouncements is actually "enshrouded in considerable smog . . . ."); Noel v. Chapman, 508 F.2d 1023, 1030 (2d Cir. 1975). In fact, we can not actually envision a reason for the outcome regarding retroactivity to differ based on whether a particular communication is a policy statement or an interpretive rule, as both are agency interpretations of regulatory schemes. Thus, to the extent we must make this choice based on the confused caselaw in this area, it seems to put form before substance.

That said, the FDA's position that it is merely clarifying its "longstanding views on preemption," 71 Fed. Reg. at 3934 — e.g., that it is only "only remind[ing the] affected parties of existing duties" — weighs heavily in favor of concluding that the Preemption Preamble is an interpretive rule. Beazer, 963 F.2d at 606. This is because, while not dispositive, the promulgating's agency's view "that a new statement is a clarification of existing law . . . is generally given much weight." Heimmermann v. First Union Mortgage Corp., 305 F.3d 1257, 1260 (11th Cir. 2002). Accordingly, we find that the Preemption Preamble merely clarifies existing law and has no prohibited retroactive effect.[18] However, we also conclude that the issue

[18]Plaintiff argues that even if the court decides it may be retroactively applied, the Preemption Preamble — published on January 24, 2006 and connected to a substantive rule due to take effect June 30, 2006 — cannot be applied because the rule is not yet in effect. (Pl's 2nd Supp. Mem. at 6-7). Defendants assert that the Preemption Preamble, unlike the substantive rule amendments to which is it attached, is an advisory opinion that cannot be understood to go "into effect." (Def. GSK's 2nd Supp. Mem. at 3; Def. Apotex's 2nd Supp. Mem. at 10-11). Neither party provided citations, and this Court's review of caselaw in and outside of the Third Circuit did not uncover anything on point. However, using principles of administrative law as our guide, we note that neither a policy statement nor an interpretive rule has the force of law. Similarly, under the FDA's own regulations, a preamble to a rule is an "advisory opinion," that

of retroactivity is not dispositive, because the Preemption Preamble is only one of several pieces of evidence which reflect the FDA's position that Plaintiff's claims are preempted. Thus, even if the Preamble is not retroactive, we would still come to the same conclusion affording deference based on the FDA's opinion as expressed in its current and prior *amicus* briefs.

2. Other Evidence Supporting Implied Preemption

As additional evidence of conflict preemption, Apotex argues that tort liability for inadequate warnings would "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives" of the FDCA. Geier, 529 U.S. at 899. First, Apotex contends that to impute liability for failing to change the label when, as part of the approval process under the ANDA, it was *required* to use verbatim the language of Defendant GSK's warning label, inherently conflicts with the FDCA. Further, Apotex urges that imposing a duty to develop or strengthen warning labels would essentially constitute a return to the drug approval scheme in place before the H-W Amendments, thus conflicting with the Act's statutory purpose to relax the generic approval process. Finally, Apotex points to numerous cases outside the Third Circuit, which has not addressed the issue, holding that the FDCA preempts state tort claims for injuries resulting from ingestion of a prescription drug. See, e.g., Needleman, 2004 WL 1773697 at *2-5 (involving the anti-depressant Zoloft); Dusek, 2004 WL 2191804 at *2-10 (involving Zoloft); Ehlis v. Shire Richwood, Inc., 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002) (involving Adderall, a drug used for treatment of ADHD in children); Abramowitz, 2006 WL 560639, at *5 (involving pain-management drug Actiq); see also C.E.R. 1988, 386 F.3d at 270; Pokorny, 902 F.2d at1123; Kanter v. Warner-Lambert Co., 99 Cal. App. 4th 780, 794 (2002); Cellucci v. Gen. Motors

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is "*not . . . a legal requirement*." 21 C.F.R. § 10.85(j) (emphasis added). Because by all accounts the preamble lacks the force and effect of law, we agree with Defendants that an effective date analysis would accordingly be irrelevant. The Preamble should be given deference as of the date it was published, January 26, 2006.

Corp., 706 A.2d 806, 811 (Pa. 1998); Guice v. Charles Schwab & Co., 674 N.E.2d 282, 289 (N.Y. 1996) (cases finding preemption but not involving the FDCA). (Def. Apotex's Mem. at 8-14; Def. Apotex's Supp. Mem. at 18-24; Def. Apotex's 2nd Supp. Mem. at 2-8).

In response, Plaintiff argues that while generic makers must rely on the innovator manufacturer's labeling and research to get initial approval, once the ANDA is approved, the regulations explicitly permit strengthening of product warning labels. 21 C.F.R. § 314.70(c)(6)(iii)(A), (D); 57 Fed. Reg. 17950, 17961. Thus, he argues the FDCA establishes a floor and not a ceiling with regards to labeling standards. He too cites to numerous cases — but also none by the Third Circuit — that have confronted this exact issue and have concluded that state failure-to-warn claims are not preempted by the FDCA and its attendant regulations. See, e.g., Hurley v. Lederle Labs. Div. of Am. Cyanamid Co., 863 F.2d 1173 (5th Cir. 1988) (noting "the great majority of United States district courts which have addressed this issue have ruled against preemption" and citing seventeen previous decisions to that effect); Laisure-Radke, 2006 WL 901657 at *3 (involving the anti-depressant Prozac); McNellis, Civ. No. 05-1286, 14 (involving the anti-depressant Zoloft); Witczak, 377 F. Supp. at 729 (involving Zoloft); Zikis, Civ. No. 04-8104, 8 (involving Zoloft); Cartwright, 369 F. Supp. at 887 (involving Zoloft); In re Paxil Litig., [docket #], 2002 WL 31375497, *1 (C.D. Cal. 2002) (involving the anti-depressant Paxil). See also Osburn v. Anchor Labs., Inc., 825 F.2d 908, 912-13 (5th Cir. 1987) (involving FDA regulations for veterinary drugs, which are very similar, if not virtually identical to the regulations regarding drugs for humans); Caraker v. Sandoz Pharm. Corp., 172 F. Supp. 2d 1018, 1032-36 (S.D. Ill. 2001) (manufacturer's common law duty under Illinois law to warn individuals of postpartum lactation-control drug's dangers was not preempted by federal law). (Pl's Response to GSK at 17-18; Pl's Response to Apotex at 6-12 Pl's Supp. Mem. at 12).

Since the Third Circuit has not confronted this issue, any caselaw cited is merely persuasive. That said, these decisions, authored by eminent jurists, are forceful, analytical, and — if the Court believed it was authorized to make the analysis — it might very well agree with them. This Court has concluded not that their analysis itself is wrong, but rather that it is improper for a federal district judge to engage in this analysis in the first place.

First, it is important to note that in contrast to the instant case, those courts had neither (1) a clear *amicus* brief from the FDA addressing the specific facts of the case before it, and representing its judgment and authority that plaintiff's common law claims are impliedly preempted (Colacicco Amicus), or (2) an express statement of policy, formally published in the Federal Register, taking the position that state law failure-to-warn claims are preempted by the FDCA (Preemption Preamble). These documents are dispositive to our determination that Plaintiff's claims are preempted.

Second, this is not a case about individual rights or Constitutional interpretation, in which judges have obligations to protect civil liberties, but is essentially a case about economics — whether a drug company should be at risk for damages because of the death of a woman taking its drugs. When Congress established the elaborate system of legislation for the introduction of new drugs, and authorized a federal agency to implement and police its operation, the resolution of claims arising out of alleged shortcomings in drug instructions and labeling should be as allowed by Congress. Congress has not provided for such claims, and the FDA has taken the position that plaintiff's claims based on state law are inconsistent with its statutory-administrative regimen. Kenneth W. Starr, *Judicial Review in the Post-Chevron Era*, 3 Yale J. on Reg. 283, 308 (1986) ("intrusions not clearly mandated by Congress or the Constitution into the processes and decisions of [a federal agency]" should be avoided because

administrative agencies are not subordinate to the federal courts in the organizational structure established by the Constitution).

It is of course true that this Court or any other trial judge with a case such as this could proceed to trial (where a jury would be required to render a verdict based on the same medical judgments considered by the FDA), and appeals by the losing party would wind their way through the court system. However, because preemption is warranted, the case should be dismissed now; if the Court is wrong, Congress can fix this error quickly, and so can the executive branch, by installing different managers at the FDA. Ultimately, this Court believes it is far more desirable that the important issues presented by this case, indeed tragic in its facts, are better addressed by elected officials, legislative and executive, than by appointed judges, a belief which itself has been echoed by the Supreme Court. See Chevron, 467 U.S. 837; Cass R. Sunstein, *Law and Administration After Chevron*, 90 Colum. L. Rev. 2071, 2088-90 (1990) ("Chevron is best understood and defended as a frank recognition that sometimes interpretation is not simply a matter of uncovering legislative will, but also involves extratextual considerations of various kinds, including judgments about how a statute is best or most sensibly implemented. Chevron reflects a salutary understanding that these judgments of policy and principle should be made by administrators rather than judges."); Laurence H. Silberman, *Chevron: The Intersection of Law and Policy*, 58 Geo. Wash. L. Rev. 821, 823 (1990) ("Chevron's importance is its recognition that . . . agencies . . . maintain a comparative institutional advantage over the judiciary in interpreting ambiguous legislation that the agencies are charged with applying."); Richard J. Pierce, Jr., *The Role of Constitutional and Political Theory in Administrative Law*, 64 Tex. L. Rev. 469, 506 (1985) (noting the Chevron Court "recognized that policy choices should be made by the most politically accountable branch of

government, and that the judiciary is the least politically accountable branch"). Further, although the facts of Chevron may have involved ambiguous terms in a statute, its principles have been consistently carried into the far reaches of administrative law, and governs this case as well. Geier, 529 U.S. at 883; Chevron, 467 U.S. at 844; Hillsborough County, 471 U.S. at 714; Horn, 376 F.3d at 180. See generally, Scalia, *Judicial Deference*, *supra*.

Also, the FDA in the Colacicco Amicus brief and in the Preemption Preamble — which we have already determined deserves considerable deference — squarely rejected Plaintiff's other arguments. The Preemption Preamble specifically analyzes and dispels the "misunderstanding" cited by numerous lower courts that FDA labeling requirements represent a minium safety standard, clarifying that the FDCA "establish[es] both a 'floor' and a 'ceiling.'" Preemption Preamble, 71 Fed. Reg at 3934-35.

Third, we find compelling Defendant Apotex' argument that, pursuant to the relaxed generic approval process mandated by the Hatch-Waxman Amendments, it was *required* to use verbatim the language of Defendant GSK's warning label during the ANDA application and approval process. Thus, assigning a duty to include a warning different from GSK's approved label inherently conflicts with the FDCA. Additionally, although many courts have held that once the ANDA is approved, 21 C.F.R. § 314.70 explicitly permits unilateral strengthening of product warning labels, the FDA now says otherwise. In its *amicus* brief, the FDA explicitly asserts that "there is no statutory or regulatory provision permitting the manufacturer to make a labeling change to its generic drug without prior FDA approval." Colacicco Amicus at 6. See also Preemption Preamble, 71 Fed. Reg at 3934-35. Presumably, this is to insure that the added language is substantiated by scientific data and if not — as would have been the case if Apotex tried to add a label linking paroxetine hydrochloride to suicidality in October 2003 — it would

have been deemed "misleading" and, thus, in violation of federal law. Colacicco Amicus at 15. Therefore, notwithstanding other lower courts' holdings that the plain language of § 314.70 seems to permit pharmaceutical manufacturers to add or strengthen warning without prior FDA approval, we interpret Geier to require us to respect the FDA's conclusion that such changes are not allowed, as the FDA is "uniquely qualified" to interpret the regulations which it is entrusted by Congress to administer. Geier, 529 U.S. at 883. Finally, we agree with the FDA's position that ensuring that warnings be scientifically substantiated is an important public policy. Dissemination of unsupported warnings risks diluting those that are scientifically supported, and/or discouraging safe and effective use of a particular drug. This could deprive patients of efficacious treatment, thereby chilling the drug's otherwise beneficial use. Colacicco Amicus at 13.

Accordingly, we find that state tort law which would hold a generic drug manufacturer liable for failing to modify a label when, pursuant to the Hatch-Waxman Amendments to the FDCA, the ANDA approval process required that the labeling be the same as that approved for the innovator drug, and a when the FDA would have deemed any post-approval enhancements "false or misleading," would actually conflict with the FDCA. For these reasons, as well as our conclusion that we must afford deference to the FDA's position that the claims are preempted, we find that Plaintiff's failure-to-warn claims are impliedly preempted.[19]

B. Effect of Buckman Co. v. Plaintiffs' Legal Committee

Finally, Defendants also urge that Buckman Co. v. Plaintiffs' Legal Committee requires that this Court find preemption in this case. We disagree.

[19]While Count XI (survival action), Count XII (wrongful death) and Count XIII (punitive damages) were not the subject of the current motions to dismiss, we now conclude, *sua sponte*, that preemption necessarily bars those claims as well.

In Buckman, the Supreme Court held that the FDCA, as amended by the Medical Device Amendments, impliedly preempted the plaintiff patients' state law "fraud-on-the-agency" claims against a manufacturer's regulatory consultant, based on statements allegedly made to the FDA in the course of seeking pre-market approval for orthopedic bone screws. Buckman, 531 U.S. at 353. Defendants argued in their briefs and at oral argument that this case stands for the proposition that the FDCA preempts the negligence *per se* claim at minimum, and possibly all Plaintiff's state tort law claims asserting inadequate warning. (Def. GSK's Mem. at 9; Apotex's Mem. at 25; Def. GSK's Supp. Mem. at 18-19; Apotex' Supp. Mem. at 24-25).

The Court agrees with Plaintiff that Buckman is distinguishable. In Buckman, the manufacturer of certain orthopedic bone devices hired a consulting company to help the manufacturer "navigat[e] the federal regulatory process." Plaintiffs brought suit not against the manufacturer, but instead alleging the defendant consultant company had defrauded the FDA in obtaining approval for the orthopedic screws. Thus, when the Supreme Court held that the claims were impliedly preempted by the FDCA, it limited this holding to the rationale that *policing fraud upon the FDA* is decidedly a federal function. Buckman, 531 U.S. at 347. Here, there is no "fraud on the FDA" alleged and there is no comparative authority permitting the FDA to police non-compliance with the warning label regulations by virtue of not affirmatively providing stronger warnings. Further, as evidence of the fact that Buckman does not usurp all state tort claims, we note that numerous post-Buckman federal cases have rejected the preemption argument for claims based on inadequate warning labels on prescription drugs. See, e.g., Laisure-Radke, 2006 WL 901657 at *3; McNellis, Civ. No. 05-1286, at 14; Witczak, 377 F. Supp. 2d at 729; Zikis, Civ. No. 04-8104, at 8; Cartwright, 369 F. Supp. 2d at 887; In re Paxil, 2002 WL 31375497, at *1; Caraker, 172 F. Supp. 2d at 1032-36. Simply stated, Buckman is

irrelevant to the preemption issues presented in this case.

VII. Issues Arising Under State Law Claims

A. Duty of Care

1. Defendant GSK: No Duty of Care Owed

However, we do not rest our dismissal of GSK on preemption alone. Because we hold that a name brand drug manufacturer does not owe a legal duty to consumers of a generic equivalent of its drug, at least for Defendant GSK, the lack of a duty of care provides a second basis for dismissing all claims against it.

Defendant GSK contends that under Pennsylvania law, "the most essential characteristic of any product liability action . . . is that the defendant manufactured or sold the product in question" and because GSK did neither, it had no direct relationship with Plaintiff or his decedent. Thus, GSK argues it owed no duty of care and therefore cannot be liable under any theory. In support of this contention, GSK cites Foster v. American Home Products, 29 F.3d 165 (4th Cir. 1994) (applying Maryland law), a case in which the Fourth Circuit held that a innovator drug manufacturer does not owe a legal duty to a consumer of a generic drug. (Def. GSK's Mem. at 3-6; Def. GSK's Reply at 4-5; Def. GSK's Supp. Mem. at 2-3, 7).

Plaintiff responds that Defendant GSK's reliance on Foster, based on Maryland law, is inapposite. First, he notes that "direct to consumer" ("DTC") advertising has dramatically expanded since Foster was decided, from $242 million in 1994 to approximately $2.38 billion in 2001, which has increased consumers' reliance on name-brand advertising, even if they actually take the generic. Second, in contrast to Maryland, in which foreseeability is the principal determinant of duty, Plaintiff contends Pennsylvania employs a more nuanced duty analysis. Specifically, Plaintiff avers that under the Pennsylvania Supreme Court's analysis in Althaus v.

Cohen, 756 A.2d 1166, 1169 (Pa. 2000), which lays out five distinct factors, including public policy, that must be considered in determining whether a duty of care exists, this Court must allow a jury to find that Defendant GSK owed a duty of care. (Pl's Response to GSK at 4-12; Pl.'s Supp. Mem. at 2-3, 6-7).

In Althaus, the Pennsylvania Supreme Court held that the determination of whether a duty exists in a particular case is rooted in public policy and involves the weighing of numerous factors, which include: (1) the relationship between the parties; (2) the social utility of the actor's conduct; (3) the nature of the risk imposed and foreseeability of the harm incurred; (4) the consequences of imposing a duty upon the actor; and (5) the overall public interest in the proposed solution. Althaus, 756 A.2d at 1169. However, while Althaus and its progeny lay out the general rubric for determining duty, the Pennsylvania courts have not specifically faced the question of whether a name brand drug manufacturer owes a legal duty to generic brand consumers. Thus, absent clear precedent, this Court must decide how it believes the Pennsylvania Supreme Court would decide the issue.

Having reviewed the caselaw nationwide, it appears that Foster, decided by the Fourth Circuit and applying Maryland law, is the single case which has confronted this issue most directly and in most detail. In Foster,[20] the parents of an infant who died after ingesting a generic drug, sued Wyeth, the manufacturer of the brand-name version of the prescription.

[20]For a detailed discussion of Foster, see Jean A. Brodie, Note, Foster v. American Home Products Corp.: Tort Liability for Injuries Caused by Someone Else's Product?, 12 T.M. Cooley L. Rev. 431, 468 (1995).

Foster, 29 F.3d at 167.[21] Wyeth moved for summary judgment on all counts, asserting, like GSK, that it could not be held liable under any theory because it did not manufacture or produce the drug taken by the deceased infant. Id. After the district court granted the motion for Wyeth on all counts, the case proceeded on appeal to the Fourth Circuit. Id. at 168.

Specifically before the Fourth Circuit was the question whether the manufacturer of a brand-name prescription drug could be held liable on a negligent misrepresentation theory for an injury caused by a generic equivalent drug manufactured by another company. Id. The court answered "no," reasoning that there is no recognized cause of action based on negligent misrepresentation against one manufacturer for injuries stemming from use of another manufacturer's product. Id. Quite simply, the circuit court found that all products liability actions *require* proof that the defendant made the product to which the alleged injuries are attributable. Id.[22] Further, the Foster court held that although the generic drug approval process requires generic manufacturers to initially use the same labeling as the previously approved innovator drug, this does not absolve them of liability for the representations made on their own drugs. Id. at 170-71. Moreover, the Foster court noted that it would be unfair to use an innovator drug manufacturer's statements regarding its drug as the basis for liability for injuries

[21]The parents had also filed suit against the generic manufacturer, but had initially mistakenly named the wrong company. In their subsequent suit against the proper manufacturer of the generic, the plaintiffs agreed to a dismissal with prejudice for reasons not stated in the record. Foster, 29 F.3d at 167.

[22]Notably, the district court had considered the negligent misrepresentation claim to be distinct from the negligence, strict liability and breach of warranty claims. While it disposed of the latter three because Wyeth was not the manufacturer, the district court refused to do so for the negligent misrepresentation claim. It only granted summary judgment based on plaintiffs' failure to prove reliance on a Wyeth representation, a necessary element of the common law tort of misrepresentation. On appeal, the Fourth Circuit found this distinction to be erroneous, clearly holding that *all* product liability actions require that the defendant have manufactured the product in question. Id. at 168.

caused by another manufacturer's drug: while the generic manufacturer reaps the financial benefits of the name brand manufacture's research and "rid[es] on the coattails of its advertising," the innovator drug manufacturer has no control whatsoever over the manufacturing or labeling of the generic substitute. Id. at 171. Finally, citing a complete lack of precedent, the Foster court concluded that a foreseeability analysis similarly did not lead to the imputation of a duty of care on the innovator drug manufacturer, because to do so would "stretch the concept of foreseeability too far." Id. In sum, it found that "Wyeth is under no duty of care to the plaintiffs." Id.

Notably, the Foster decision has encountered widespread acceptance; a review of caselaw reveals that every state and federal district court which has confronted the issue of innovator drug-manufacturer liability has either adopted the Foster reasoning or cited Foster with approval. See Tarver v. Wyeth, Inc., Civil Action No. 3-04-2036, slip. op. (W.D. La. Apr. 28, 2005) (applying Louisiana law); Block v. Wyeth, Inc., 02-cv-1077, 2003 WL 203067 (N.D. Tex. Jan. 28, 2003) (under Texas law); DaCosta v. Novartis AG, 01-cv-800, 2002 WL 31957424 (D. Or. Mar. 1, 2002) (applying Oregon law); Christian v. 3M, 126 F. Supp. 2d 951, 958 (D. Md. 2001) (applying Maryland law); Miller v. Bristol-Myers Squibb Co., 121 F. Supp. 2d 831, 836 (D. Md. 2000) (applying Maryland law); Sharp v. Leichus, 2004-CA-0643, 2006 WL 515532 (Fla. Cir. Ct. Feb. 17, 2006); Kelly v. Wyeth, MICV 2003-03314-B, slip. op. (Super. Ct. Mass. May 6, 2005); Sheeks v. Am. Home Prods. Corp., No. 02CV337, slip. op. (Dist. Ct. Colo. Oct. 15, 2004); Sloan v. Wyeth, Inc., No. MRS-L-1183-04, slip. op (Super. Ct. N.J. Oct. 13, 2004); Beutella v. A.H. Robins, Civil No. 980502372, slip. op. (Utah Dist. Ct. Nov. 7, 2001).

While this Court is of course not bound by Foster and its progeny, we — like our sister courts across the nation — find it persuasive and adopt its holding. First, although Maryland law

differs slightly from Pennsylvania's as to ascertaining a duty of care and as to the elements of certain product liability theories (e.g., strict liability), it is the same with respect to an essential and elementary characteristic of product liability law: both states require that the defendant manufacture or sell the product in question. See, e.g. Hahn, 673 A.2d at 891 (product liability claim can only be brought against "a manufacturer" of the drug in question); Mellon v. Barre-Nat'l Drug Co., 636 A.2d 187, 191-92 (Pa. Super. 1993) ("In general, a defendant must be identified as the manufacturer, distributor, or seller of the offending product before the injuries suffered by the plaintiff may be found to be proximately caused by some negligent act or omission of the defendant.").[23] Furthermore, even though foreseeability is the principal determinant of duty in Maryland, Foster indirectly touches on most, if not all, of the Althaus factors. Specifically, we agree that to impose a duty in this case "would be to stretch the concept of foreseeability too far," as GSK cannot reasonably expect that consumers will rely on information they provide when actually ingesting another company's drug. Foster, 29 F.3d at

[23]This concept is well-settled under Pennsylvania law. See, e.g., Soldo v. Sandoz Pharm. Corp., 244 F. Supp. 2d 434, 524 (W.D. Pa. 2003) ("Absent a causal relationship between the *defendant's product* and the plaintiff's injury the defendant cannot be held liable on a theory of negligence, strict product liability, or misrepresentation."); Long v. Krueger, Inc., 686 F. Supp. 514, 517 (E.D. Pa. 1988) ("In a product liability case, the *plaintiff must identify the defendant as the manufacturer or seller of the offending product* before a plaintiff's injuries may be found to be proximately caused by the negligence of the defendant."); Klein v. Council of Chem. Ass'ns, 587 F. Supp. 213, 222-23 (E.D. Pa. 1984) (dismissed for failure to state a claim because plaintiff was unable to identify the product(s) that caused his injuries and, in turn, he could not identify which if any of the named defendant manufacturers created the product); Layton v. Blue Equip. Co. of Can., Ltd., 599 F. Supp. 93, 95 (E.D. Pa. 1984) (granting summary judgment for defendants because plaintiff did not identify the manufacturer of the lift-jack that allegedly injured her); Incolligno v. Ewing, 282 A.2d 206, 219 (Pa. 1971) ("companies which *make and sell drugs* . . . [must be held] to a high degree of responsibility.") (overruled as to another point of law); Cummins v. Firestone Tire & Rubber Co., 495 A.2d 963, 967-68 (Pa. Super. 1985) (general rule under Pennsylvania law is that plaintiff *must identify a defendant as the manufacturer or seller of the product* that caused plaintiff's injury before he may establish that the injuries were proximately caused by defendant's negligence and "[a]bsent such identification, there can be no . . . liability").

171. Also, we agree that unfair consequences would result if we were to impose a duty upon GSK, when it obtained no benefit from the sale of Apotex's generic equivalent and had no control over the manufacturing or labeling of paroxetine hydrochloride, yet it bore the expense of developing Paxil from which Apotex materially benefits. Id. at 170.

To the extent that Pennsylvania law on the existence of duty requires the additional consideration of public policy, this does not advance Plaintiff's claims against GSK. Contrary to Plaintiff's assertion that this Court is free to divine its own interpretation of public policy, in fact, Pennsylvania courts generally ascertain public policy "by reference to the laws and legal precedents and not from general considerations of supposed public interest." Prudential Prop. & Cas. Ins. Co. v. Colbert, 813 A.2d 747, 752 (Pa. 2002); Shick v. Shirey, 716 A.2d 1231, 1237 (Pa. 1998). As Defendant GSK correctly argues, Pennsylvania courts have recognized the societal importance of new and effective prescription drugs, Gile v. Optical Radiation Corp., 22 F.3d 540, 546 (3d Cir. 1994). To encourage this process, the courts have also recognized the need not to unduly burden the pharmaceutical industry with unfettered liability. Hahn, 673 A.2d at 89-91 (holding, on policy grounds, that a strict liability claim should not lie against drug manufacturer); Incollingo v. Ewing, 282 A.2d 206, 220 (Pa. 1971) (holding pharmaceutical *manufacturers* to a high degree of responsibility) (emphasis added).[24] In addition to evincing policy, this also suggests the "social utility" and "consequences of imposing a duty" prongs in

[24]In contrast, we reject Plaintiff's contention that Pennsylvania's policy of holding pharmaceutical *manufacturers* to a high degree of care supports imputing a duty of care to GSK. Incolligno, 282 A.2d at 219. In fact, Incolligno merely reiterates that idea that "companies which *make and sell drugs* . . . [must be held] to a high degree of responsibility . . . for any failure to exercise vigilance commensurate with the *harm which would be likely to result* from relaxing it." Id. (emphasis added). Thus, Incollingo supports the idea, as discussed *supra*, that the actual maker of the drug — in this case Apotex — should be held to have a duty of care to consumers. It is erroneous to assert that Incollingo supports the proposition that public policy is served by holding GSK liable for injuries stemming from use of Apotex's product.

Althaus weigh against finding a duty owed by GSK. Additionally, the courts and legislature of the Commonwealth have evinced a policy of deference to any well-defined public policy embodied by federal law. See State Farm Mut. Auto. Ins. Co. v. Foster, 889 A.2d 78, 80-81 (Pa. 2005) ("the legislative concern for the increasing cost of automobile insurance is the public policy to be advanced by statutory interpretation of the MVFRL"); In re Estate of Wagner, 880 A.2d 620, 626 (Pa. 2005) (holding that the statute creating "child death reviews" to be conducted by the Department of Public Welfare clearly expressed public policy to identify remedial possibilities and better safeguard children, which purpose could not be accomplished if agencies feared making discoverable admissions that could lead to liability, dictated outcome that audits could not be available to plaintiffs as discovery); see also Acands, Inc. v. Travelers Cas. & Sur. Co., 435 F.3d 252, 258 (3d Cir. 2006) ("courts may refuse to enforce arbitration awards that violate well-defined public policy as embodied by federal law."). More specifically, like the federal courts discussed above, the Pennsylvania courts and legislature have shown deference to the FDCA. They have viewed the FDCA as indicia of a federal policy that in the area of prescription drugs, the FDA is uniquely qualified to decide whether state law stands as an obstacle to the objectives of Congress. See White v. Weiner, 562 A.2d 378, 383 (Pa. Super. Ct. 1989) (stating that "our legislature unequivocally has expressed a policy of deference to the federal scheme in the area of drug labeling . . . and we can ascertain no reason not to extend that policy to civil cases raising misbranding claims"); see also Horn, 376 F.3d at 171 (applying Pennsylvania law); Gile, 22 F.3d at 546 (applying Pennsylvania law). Further, the fact that Congress created the FDA in the first place, and the statutory scheme embodied in the FDCA, demonstrates that it believes the public interest is best served by the FDA's weighing of the risks and benefits of a particular prescription drug. These federal policies, when analyzed in

conjunction with the other factors under Althaus, militate against finding a duty of care owed by GSK.

Like in Foster, Plaintiff in this case invites this Court to drastically expand the boundaries of Pennsylvania tort law without precedent or policy to support his position.[25] We believe the Supreme Court of Pennsylvania would not accept this invitation, and accordingly, we decline to do so as well. Thus, this Court holds that under Pennsylvania law, there is no duty of care owed by a brand-name prescription drug manufacturer to a plaintiff allegedly injured by a generic equivalent drug manufactured by another company. Thus, even if this Court's conclusion regarding preemption were found to be improper, the claims against Defendant GSK must still be dismissed.[26]

2. Defendant Apotex: Duty of Care Owed

Defendant Apotex asserts that it was not responsible for the form or substance of the labeling connected with paroxetine hydrochloride, and therefore it too did not owe a duty of care

[25]In Bilt-Rite Contractors, Inc. v. Architectural Studio, 866 A.2d 270, 285 (Pa. 2005), the Pennsylvania Supreme Court held that an architect who supplied information and services to a contractor for pecuniary gain, knowing it would be relied upon by the contractor in bidding on a construction project, would be held to have a duty of care even though privity of contract was lacking. Id. Further, the court held that the economic loss rule does not bar recovery for negligent misrepresentation in such a case. Id. Plaintiff argues for a broad reading of Bilt-Rite, contending that it supports finding that GSK owed a duty of care, even though it did not manufacture the drug in question. The Court understands Bilt-Rite to have a narrower holding, adopting § 552 of the Restatement of Torts (Second) only as it applies to "architects and other design professionals." Bilt-Rite, 866 A.2d at 286. Further, "given the important reliance placed upon . . . professional services," the Bilt-Rite court also recognized the importance of the fact that the seller was a professional. Finally, Bilt-Rite was confined to a situation where purely economic damages were alleged, and thus the holding was a specific exception to the economic loss rule. Here, Defendant GSK is not in the business of designing and/or building homes, the various policy reasons behind liability for "design professionals" are simply inapplicable to a drug manufacturing company, and economic loss is not at issue. In sum, Bilt-Rite is inapplicable to the present case.

[26]Again, while Counts XI-XIII were not the subject of Defendants' motions to dismiss, the lack of a duty of care owed by GSK bars those claims as well.

to Plaintiff that would give rise to liability against it. For the reasons that follow, this contention must be rejected.

In making this argument, Apotex focuses on the H-W Amendments, which allow a generic maker to rely on the innovator's testing and require it to use identical labeling as the innovator in order to obtain FDA approval. Thus, Apotex argues that, "like a pharmacist who assembles the components of a drug prescribed by a physician," its only duty with respect to labeling was to attach a label which was the same as that approved for Paxil, which it did. As for a more generalized duty, Apotex cites to foreseeability and public policy, two critical factors in the Althaus duty analysis. It urges: (1) the H-W Amendments made it unforeseeable that it could be held liable for inadequacies in labels it did not create, and (2) the H-W Amendments are a clear policy expression by Congress to avoid imposing a duty on generic manufacturers. Further, distinguishing Foster, Apotex takes the position that because the generic manufacturer was no longer a party to the suit when the case was decided, the Fourth Circuit's holding that the generic manufacturer owes a duty of care to consumers who ingest its drug is mere *dicta*. (Def. Apotex's Mem. at 5-9; Def. Apotex's Supp. Mem. at 7-18, 25-29).

Plaintiff counters that quite simply, Apotex, like all product manufacturers, cannot escape the duty it owes to all its consumers. This is because it has a very direct relationship with them: it makes and labels the drug they take. (Pl.'s Resp. at 4-6).

In deciding whether Apotex owed Plaintiff a duty of care, we address the Althaus factors in turn. As a threshold matter, Apotex challenges the first Althaus factor, the relationship between the parties. Citing Makripodis v. Merrell-Dow Pharmaceuticals Inc., 523 A.2d 374, 377 (Pa. Super. 1987), in which the court held that a pharmacist who properly dispenses a prescription ordered by a physician owes no duty to consumer, Apotex suggests that similarly, it

is merely an intermediary who passed along the warning label already prepared by GSK. This Court believes that this endeavor to liken itself to a mere middleman misses the mark. We agree with Plaintiff that Apotex's attempts to distance itself from consumers of its drugs obfuscates the direct relationship that it has with persons who ingest the very drug *Apotex* makes and *Apotex* sells: paroxetine hydrochloride, with the very labels *Apotex* attaches to it. Further, that all manufacturers owe a duty of care to their customers is among the most basic tenets of product liability law, and Apotex cites no caselaw to the contrary. See, e.g., Hahn, 673 A.2d at 891; Incolligno, 282 A.2d at 219. Thus, we find this direct relationship, if not dispositive, weighs heavily in favor of finding a duty.

Moreover, we find the Foster court's discussion of generic manufacturer liability — specifically foreseeability and public policy — compelling. While it is true that the ANDA process requires generic manufacturers to use the same labeling as the previously approved innovator drug, we cannot agree that this absolves them of liability for the representations made on their own drugs. That basic tort concepts always hold a manufacturer liable for its products makes liability based on inadequate labeling foreseeable to Apotex. Nor can we agree that the H-W Amendments are a clear policy expression by Congress to avoid imposing a duty on generic manufacturers or made it unforeseeable that Apotex could be held liable for inadequacies in its *own* labels. If that was Congress' intent, it or the FDA would have said so. Moreover, Plaintiff's argument that this portion of Foster is *dicta* is irrelevant, as we have already acknowledged that Foster has no controlling effect on this court. Whether *dicta* or not, we look to this part of Foster for its *reasoning*, and because this reasoning is well-articulated and persuasive, this Court adopts it.

Finally, the last two Althaus factors — the social utility of the actor's conduct, and the

consequences of imposing a duty upon the actor — do not weigh against finding a duty owed by Apotex. While one could argue that there is social utility in making less-expensive, generic substitutes available to the public, this Court is mindful of the fact that Apotex is still a business, manufacturing drugs like paroxetine hydrochloride not for some altruistic reason, but to realize a profit. Apotex reaps the financial rewards of selling paroxetine hydrochloride, and it cannot hide from liability by crying regulatory foul. Also, the economic consequences of imposing a duty upon Apotex are marginal, given that a duty of care is imposed on all product manufacturers. See, e.g., Hahn, 673 A.2d at 891; Incolligno, 282 A.2d at 219. Accordingly, we hold that Apotex owed a duty of care to Plaintiff and Plaintiff's decedent, sufficient to give rise to liability against it.

B. Learned Intermediary Doctrine

A third ground cited by Defendants for dismissing the entire complaint, which we reject at this stage of the litigation, is the "learned intermediary" doctrine ("LID"), under which a drug manufacture's liability is based on its warning labels targeted at doctors, not consumer-patients. (Def. Apotex's Mem. at 16; Def. GSK's Supp. Mem. at 22-26; Def. Apotex's Supp. Mem. at 37-40). Plaintiff counters that the LID does not apply because: (1) he has plead that Defendants failed to provide adequate warnings to among others, decedent's treating and/or prescribing physician, Compl. at ¶86, and (2) the doctrine requires an analysis of the adequacy of the warnings, a question of fact which cannot be determined at this early stage. Further, citing Perez v. Wyeth Labs, 734 A.2d 1245 (N.J. 1998), Plaintiff counters that a direct-to-consumer ("DTC") advertising exception should apply to the LID. Perez, 734 A.2d at 1257 (concluding that, when mass marketing seeks to influence a patient's choice of a prescription drug, a pharmaceutical manufacturer should not be unqualifiedly relieved of a duty of care and thus adopting the DTC

advertising exception to the LID). He notes that Defendant GSK directly advertised its product extensively to consumers and that both Plaintiff's decedent and her prescribing physician were aware of and relied upon warranties from the drug company. (Pl.'s Response to GSK at 7-8; Pl.'s Response to Apotex at 13; Pl.'s Supp. Mem. at 15-17). Defendant GSK replies that to the extent the LID necessitates a determination of adequacy, this does not preclude dismissal at the 12(b)(6) stage, because adequacy may be presumed based on the FDA's grant of original approval and subsequent numerous approvals of Paxil for additional uses. (Def. GSK's Supp. Mem. at 22).

Under Pennsylvania's LID, a prescription drug manufacturer meets its duty to warn by providing an adequate warning to a "learned intermediary" (usually a physician) as opposed to the public or individual patient-consumers. Mazur v. Merck & Co., 964 F.2d 1348, 1355 (3d Cir. 1992); Baldino v. Castagna, 478 A.2d 807, 810 (Pa. 1984); Lineberger v. Wyeth, No. 001484, 2006 WL 416273, *7 (Pa. Super Feb. 23, 2006). Thus, for drugs available only by prescription, warning labels are targeted at doctors, not individual users. Id. The foundation of this doctrine was announced by the Pennsylvania Supreme Court in Incollingo v. Ewing, 282 A.2d 206, 220 (Pa. 1971). In Lebowitz v. Ortho Pharmaceutical Corp., 307 A.2d 449 (Pa. Super. 1973), the Superior Court discussed the rationale - namely, that it is for the prescribing physician to consider warning labels supplied by the drug manufacturer, as well as other medical literature and sources and the personal medical history of his or her patient, in coming to an *independent medical judgment* whether to prescribe the medication in question. Id. at 457. The intended user in a case involving a prescription drug is the prescribing physician precisely because of the nuanced decision a doctor must make. Id.; Makripodis, 523 A.2d at 377 (stating each individual for whom a prescription drug is prescribed is a unique organism who must be examined by a

physician who is aware of the nature of the patient's condition as well as his or her medical history). The LID is strictly applied by Pennsylvania courts. White, 562 A.2d at 384-85 (stating "[i]n a line of cases beginning with Incollingo v. Ewing, . . . our courts consistently have stated that a drug manufacturer's duty to warn extends only to the prescribing physician, and not to the ultimate consumer.").

Nonetheless, we conclude the LID does not bar any of Plaintiff's claims at this stage of the litigation.[27] While we agree with Defendants that pursuant to the LID, warning labels are targeted at doctors, not consumer-patients, in fact, Plaintiff properly plead that Defendants failed to provide adequate warnings to his decedent's treating and/or prescribing physician. Compl. at ¶86.

Further, the doctrine only applies if the facts support the conclusion that a drug manufacturer *adequately* warns doctors of a drug's dangers; it does not shield drug manufacturers from liability if the warnings they provided to physicians would not permit the physicians to adequately advise their patients. See, e.g., Amore v. G.D. Searle & Co., 748 F. Supp. 845, 850 (S.D. Fla. 1990). Thus, as Plaintiff correctly argues, the Court must undertake an analysis of the sufficiency of the warnings. Makripodis, 523 A.2d at 378 ("an action against a drug manufacturer based upon inadequate warnings, the issue to be determined is whether the warning, if any, that was given to the prescribing physicians was proper and adequate."). See also Brecher v. Cutler, 578 A.2d 481, 485 (Pa. Super. 1990). This cannot be done at the 12(b)(6) stage because the representations of the decedent's doctor as to whether, if at all, she relied upon

[27]In Part VII.D.1.b.ii *infra*, we hold that the LID bars Plaintiff's claim under the New York consumer protection statute. However, we make that decision for reasons entirely different from those discussed here, because of the nature of a consumer protection statute requires it.

these warnings is not in the record.[28] Accordingly, the applicability of the learned intermediary doctrine is more appropriate in a motion for summary judgment.[29] See, e.g., Cahill v. Miles, Inc., 91-cv-1966, 1992 WL 110537 (E.D. Pa. 1992) (summary judgment entered for drug manufacturer where record demonstrated that defendant warned of specific adverse side effects suffered by plaintiff); Ferrera v. Berlex Labs., Inc., 732 F. Supp. 552, 555 (E.D. Pa. 1990) (same); Brecher, 578 A.2d at 485 (same); Taurino v. Ellen, 579 A.3d 925, 927-28 (Pa. Super. 1990) (LID bars products liability claim on summary judgment where adequacy of warning was conceded by plaintiff). Accordingly, this Court will not dismiss any of Plaintiff's claims at this

[28]We consider the exhibits to Plaintiff's amended complaint which demonstrate that there was no warning as to an association between the drug and suicidality in October 2003. Specifically, plaintiff attached the "Prescribing Information" available in July 2003 for Paxil/paroxetine hydrochloride (Amd. Compl., Exhibit A), as well as the 2003 description of paroxetine hydrochloride available through Micromedex (Amd. Compl., Exhibit C). While the general rule is that a court may not consider evidence outside the pleadings for a 12(b)(6) motion without converting it to a summary judgment motion, the Third Circuit has held that a court may properly consider a concededly authentic document upon which the complaint is based. Pension Benefit Guar. Corp., 998 F.2d at 1196. First, where Plaintiff's entire complaint is based on failure-to-warn, clearly the warnings themselves are documents upon which the complaint is based. Second, it has never been disputed by the parties that no such warning was included in October 2003. Id. However, neither evidence as to what Defendants knew nor the extent to which decedent's doctor relied upon these warnings is in the record.

[29]We note that generally, whether a particular warning is "adequate" is a question of fact to be resolved by a jury. See Dougherty v. Hooker, 540 F.2d 174, 182 (3d Cir. 1976). Defendants, however, argue that adequacy of the warning is a question of law and cite Davis v. Berwind Corp., 690 A.2d 186, 190 (Pa. 1997) and Demmler v. SmithKline Beecham Corp., 671 A.2d 1151, 1154 (Pa. Super. Ct. 1996) in support of that proposition. (Def. Apotex' Supp. Mem. at 38; Def. GSK's Supp. Mem. at 24). However, Defendants oversimplify the principles articulated by those courts. In fact, both cases state that the adequacy question is only *initially* a question of law, citing precedents that demonstrate that the full analysis requires a two-step inquiry. The court must first determine as a threshold issue whether recovery would possibly be justified under the plaintiff's version of the facts - e.g. the question of law. Mackowick v. Westinghouse Elec. Corp., 575 A.2d 100, 103 (Pa. 1990). It is ultimately the trier of fact that must decide whether a particular warning was adequate based on the particular facts of the case - e.g. the actual adequacy question is of fact. Id. at 103. Further, "[g]enerally, expert medical testimony is required to determine whether the drug manufacturer's warning to the medical community is adequate," which we do not have at the motion to dismiss stage. Demmler, 671 A.2d at 1154.

juncture based on the learned intermediary doctrine.[30]

C. Reach of Hahn v. Richter

Finally, Defendants argue that in addition to barring Plaintiff's strict liability claim, the broad holding announced by the Pennsylvania Supreme Court in Hahn v. Richter, 673 A.2d 888, 891 (Pa. 1996), precludes all Plaintiff's claims except those based in negligence. (Def. GSK's Supp. Mem. at 6; Def. Apotex's Supp. Mem. at 11-12). We agree with this proposition. At least with regard to Plaintiff's non-negligence claims, it provides another basis for dismissal.

In Hahn, in barring a strict liability claim against a manufacturer of a prescription drug, the Pennsylvania Supreme Court broadly held that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, i.e., the manufacturer's negligence, is the only recognized basis of liability." Hahn, 673 A.2d at 891. That is, the court held that because prescription drugs are inherently dangerous, a drug manufacturer only has the duty to exercise reasonable care to inform its intended user of the qualities that make it dangerous. Id. at 890 (adopting comment k of the Restatement (Second) of Torts § 402A, which denies application of strict liability to

[30]If we reached the merits of the LID issue, any direct-to-consumer ("DTC") advertising exception would likely not apply. This is because, in the eight years since Perez, the New Jersey Supreme Court case making an exception to the LID for direct-to-consumer advertising, was decided, no state has joined New Jersey. In re Norplant Contraceptive Prods. Liab. Litig., 165 F.3d 374, 377 (5th Cir. 1999) (holding that DTC exception to the learned intermediary doctrine should not be created); In re Meridia Prods. Liab. Litig., 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004) (same). Pennsylvania courts that have considered the issue have expressly rejected the argument. See Heindel v. Pfizer, Inc., 381 F. Supp. 2d 364, 378 (D.N.J. 2004) (applying PA law); ex rel. Lennon v. Wyeth-Ayerst Labs., Inc., 2001 WL 755944, *2 (Pa. Super. June 14, 2001); Albertson v. Wyeth Inc., 63 Pa. D. & C. 4th 514, 539, 2003 WL 21544488, *11 (Pa. Com. Pl. 2003) (although Wyeth engaged in direct-to-consumer advertising, defendant's preliminary objections were sustained because pursuant to the learned intermediary doctrine, defendants had no duty to disclose any information directly to plaintiff); Luke v. Am. Home Prods. Corp., 1998 WL 1781624, *4-5 (Pa. Com. Pl. 1998) (same). Thus, absent an intervening change in the applicable law, in this Court's view, Pennsylvania law does not provide any exception to the LID based on direct-to-consumer advertising.

"unavoidably unsafe products" such as prescription drugs and finding § 388, which applies to "chattel known to be dangerous for intended use," to provide the proper standard of care); see also Mazur, 964 F.2d at 1353-55 (interpreting Incollingo and Baldino as requiring a prescription drug manufacturer's liability for failure-to-warn rest on negligence, not strict liability); Baldino, 478 A.2d at 810; Incollingo, 282 A.2d at 220 n.8.

While Plaintiff admitted on the record at oral argument that all his claims were based on Defendant's failure-to-warn, Plaintiff nonetheless argues that, in fact, Hahn does not control because that court presumed the products were marketed with *proper warnings*, whereas here Plaintiff *challenges* the adequacy of the warnings. (Pl's Response to GSK at 18-19; Pl's Supp. Mem. at 3-5). We find this contention to be without merit. First, the court's broad statement that negligence is the only recognized basis of liability any time "where the adequacy of warnings associated with prescription drugs *is at issue*" unambiguously demonstrates the holding applies to all failure-to-warn claims, which inherently call into question the adequacy of prescription drug warnings. Second, the Hahn court did not just carelessly pronounce a broad holding. Instead, it relied on a well-developed line of cases, including Mazur, Incollingo, and Baldino, to come to its conclusion. Also, and importantly, the court took great pains to explain *why* failure to exercise reasonable care is the only cause of action that should be permitted for claims which are based on failure-to-warn. Quoting comment k of the Restatement (Second) of Torts § 402A, the court reasoned that prescription drugs "supply the public with . . . apparently useful and desirable product[s]," which protect against serious and even deadly diseases. Hahn, 673 A.2d at 890, n.2. This, explained the court, "fully justifie[s]" the marketing and use of prescription drugs, "notwithstanding the unavoidable high degree of risk which they involve." Id. Third, Hahn's authority for this proposition has not been questioned.

We therefore hold that Hahn requires us to dismiss Count IX (strict liability), as well as all of Plaintiff's remaining claims except the four that sound in negligence: negligent misrepresentation (Count IV), negligent infliction of emotional distress (Count VI), negligence (Count VII), and negligence per se (Count VIII). Accordingly, Count II (breach of implied warranty), Count III (fraud by intentional misrepresentation and violation of New York consumer protection law), Count V (intentional infliction of emotional distress), and Count IX (strict products liability) must be dismissed.[31]

D. Individual Causes of Action

Assuming *arguendo* that Plaintiff's claims were not barred by preemption, lacking duty of care, and/or the reach of Hahn, or this Court's holding as to any or all of those issues were found to be erroneous, Defendants would have to respond to the following arguments pertaining to Plaintiff's individual causes of action. We therefore address each seriatim.

1. Non-negligence Claims

a. Breach of Implied Warranty (Count II)

First, citing the Pennsylvania Superior Court's decision in Makripodis v. Merrell-Dow Pharmaceuticals Inc., 523 A.2d 374 (Pa. Super. 1987), Defendant Apotex contends that a claim for breach of implied warranty is not available in cases involving prescription drugs under Pennsylvania law. (Def. Apotex's Mem. at 17). Plaintiff argues his implied warranty claim is viable, urging that Makripodis can be distinguished in that it involved a claim against a pharmacy, not a drug manufacturer. (Pl's Response to Apotex at 14).

In dismissing a claim for the implied warranty of merchantability against a retail

[31]Hahn would also bar Plaintiff's original Count I (breach of express warranty), which Plaintiff voluntarily withdrew at oral argument. However, as Plaintiff's Amended Complaint does not reflect this, we want to clarify that even had Plaintiff not dropped it, the breach of express warranty claim (Count I) would not survive anyway.

pharmacist, the Makripodis court broadly stated that "the very nature of prescription drugs . . . precludes claims for breach of the implied warranty of merchantability." Makripodis, 523 A.2d at 377. See also Murray v. Synthes, Inc., 1999 WL 672937, *9 (E.D. Pa. Aug. 23, 1999) (relying on Makripodis, refusing leave to amend complaint to add an implied warranty claim for prescription medical device). The court reasoned this is because a generalized warranty is not appropriate given that each person for whom a drug is prescribed "is a unique organism who must be examined by a physician who is aware of the nature of the patient's condition as well as the medical history of the patient." Makripodis, 523 A.3d at 377.

We concur with Defendants that Makripodis bars Plaintiff's implied warranty claim. As a court sitting in diversity, we must apply state law. Here, the Superior Court unambiguously held that persons or entities providing prescription drugs can not be held liable for the breach of implied warranty. Further, we find Plaintiff's contention that Makripodis does not apply because the case involved a claim against a pharmacy instead of a drug manufacturer to be without merit. The Makripodis court based its decision not on who the defendant was, but rather on the inherently dangerous "nature of prescription drugs." Id. It is precisely because of the risks posed that such drugs may be obtained only upon the prescription of a licensed physician and that imposition of a warranty of fitness for ordinary purposes is inappropriate. Accordingly, this Court must preclude Plaintiff's claim for breach of the implied warranty of merchantability. Even if Plaintiff's complaint was not otherwise barred, Count II would still be dismissed.

b. Fraud by Intentional Misrepresentation and Violation of New York Consumer Protection Act (Count III)

In his Amended Complaint, Plaintiff consolidated the two prior Counts III and X (asserted against both Defendants) into a single new Count III, which sets forth both fraud and

violation of New York consumer protection law claims against Defendant GSK only. GSK asserts that both must be dismissed. For the reasons that follow, we disagree that the fraud portion should be dismissed, but agree as to the New York Consumer Protection portion of the count.

i. Fraud

The elements of fraud by intentional misrepresentation under Pennsylvania law are: (1) a representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and, (6) the resulting injury was proximately caused by the reliance. Murray, 1999 WL 672937 at *3; Bortz v. Noon, 729 A.2d 555, 560 (Pa. 1999); Gibbs v. Ernst, 647 A.2d 882, 889 (Pa. 1994). The tort of intentional non-disclosure has the same elements, except that in the case of an omission, the party intentionally conceals something rather than making an affirmative misrepresentation. Bortz, 729 A.2d at 560.

Defendant GSK argues that Plaintiff's fraud claim lacks the required particularity under F.R. Civ. P. 9(b). Specifically, Defendant GSK asserts the fraud claim must be dismissed because Plaintiff has failed to allege that decedent's prescribing physician relied on any particular statement or information provided by GSK. (Def. GSK's 3rd Supp. Mem. at 2-4).

In contrast to the original Complaint, Plaintiff's Amended Complaint includes numerous specific allegations that all information available about Paxil or its generic equivalent was disseminated by GSK, and that this information was justifiably relied upon by the decedent and her physician. This specificity can be found in the following paragraphs of the Amended Complaint:

> 28. During [a conversation the physician had with Mrs. Colacicco about the risks of taking paroxetine], Lois was advised that there were no "obvious interactions" between paroxetine and Lorazepam "identified in Micromedex," which is a healthcare research engine that provides drug summaries for physicians.
>
> 32. Any and all knowledge that Lois Colacicco's physicians possessed concerning Paxil came from the following sources, which either contained or were the direct result of GSK's manipulated data, material misrepresentations and omissions, and inadequate warnings concerning Paxil: [the 2003 Physicians Desk Reference, the Micromedex, GSK's sales representatives, GSK's website, and GSK's advertisements].
>
> 35. When Lois Colacicco's . . . physicians decided to prescribe Paxil . . . they *based their decisions solely upon the aforesaid manipulated data, false promotion and incomplete warnings*.
>
> 36. . . . There was no information available at that time about the drug that Lois Colacicco was taking other than what had been promulgated and disseminated by GSK.
>
> 37. Lois Colacicco . . . and her . . . *physicians justifiably relied upon all of the information* that had been promulgated and disseminated by GSK.
>
> . . .

Amended Compl. at ¶ 28, 32, 35-37 (italics added). Thus, based on the allegations alone, had the claims against GSK not been dismissed earlier for preemption and lack of a duty of care, and had we not found that Hahn precluded Plaintiff's non-negligence claims, the fraud portion of Count III would survive.

ii. Violation of New York Consumer Protection Law

Plaintiff also alleges in Count III that "by engaging in deceptive acts and practices and false advertising," Defendant GSK violated section 349 of the New York Consumer Protection Law. Amd. Compl. at ¶ 40; N.Y. Gen. Bus. Law § 349.

A prima facie case for recovery under section 349 of the statute for "deceptive acts or practices" requires a showing that defendant is engaging in an act or practice that is deceptive or misleading in a material way and that plaintiff has been injured by reason thereof. Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, 85 N.Y.2d 20, 25 (1995). See also

Leider v. Ralfe, 387 F. Supp. 2d 283, 292 (S.D.N.Y. 2005). The allegedly deceptive acts, representations or omissions "must be misleading to a reasonable consumer." Oswego, 85 N.Y.2d at 26. Finally, a claim under the New York consumer protection law requires proof that the defendant's acts are directed at consumers. Id.; Goshen v. Mutual Life Ins. Co. of N.Y., 774 N.E.2d 1190, 1196 (N.Y. 2002).

Although not pleaded by Plaintiff, to assert a cause of action for false advertising under section 350, a plaintiff must demonstrate that the advertisement: (1) had an impact on consumers at large; (2) was deceptive or misleading in a material way; and (3) resulted in injury. Andre Strishak & Assocs., P.C. v. Hewlett Packard Co., 300 A.D.2d 608, 609 (N.Y. App. Div., 2d Dep't 2002). In determining whether an advertisement is "false" within the meaning of the statute prohibiting false advertising, the test is whether the advertisement is likely to mislead a reasonable consumer acting reasonably under the circumstances. Id. Additionally, reliance is a element of a claim under section 350. Leider, 387 F. Supp. 2d at 292. Otherwise, while specific to false advertising, the standard for recovery under N.Y. Gen. Bus. Law § 350 is identical to N.Y. Gen. Bus. Law § 349. Goshen, 774 N.E.2d at 1195.

First, Defendant GSK contends that insofar as Plaintiff alleges that GSK engaged in false advertising, that portion of Plaintiff's claim should be dismissed because: (1) false advertising claims fall under N.Y. Gen. Bus. Law § 350, and (2) Plaintiff has not plead under section 350 or alleged the required reliance on any specific advertisement. Second, while not entirely clear, GSK appears to argue that the New York Consumer Protection Law is inherently inconsistent with the learned intermediary doctrine. Finally, citing Gray v. Seaboard Securities, Inc., 788 N.Y.S.2d 471, 472 (N.Y. App. Div. 2005), GSK suggests that inadequate warning claims are not actionable under the consumer protection law because they are analogous to securities violations,

for which New York law provides no relief. (Def. GSK's 3rd Supp. Mem. at 4-6).

Plaintiff counters that he sufficiently plead actual reliance on GSK's materials, and that Defendant's contention that its conduct was not aimed at consumer-patients, or that recovery under state consumer protection laws is somehow barred by the learned intermediary doctrine, is belied by the very nature of "direct-to-consumer" advertising. Further, Plaintiff attempts to distinguish Gray, noting that court sought to avoid allowing additional protections beyond those afforded under the federal Securities Exchange Act, while the FDCA offers no such protection. (Pl's Response to Apotex at 19-20; Pl's 3rd Supp. Mem. at 4-5).

To the extent that Plaintiff has accused GSK of engaging in false advertising," while we find that Plaintiff sufficiently plead actual reliance, we agree that this allegation necessarily must fall under N.Y. Gen. Bus. Law section 350.[32] Plaintiff improperly plead his entire Count alleging violation of the New York Consumer Protection Law under section 349. Thus, the portion of Plaintiff's Count III alleging false advertising under New York's Consumer Protection Law must be dismissed. However, even if he had alleged a violation of section 349, it would still be sufficient.

[32]GSK acknowledges that some caselaw suggests that a false advertising claim can be brought under either section 349 or section 350 (but provided no citations to this effect). However, it argued that even if there are any, this interpretation is erroneous as this would render section 350 totally superfluous. Plaintiff did not address this contention at all. This court reviewed the caselaw and found that while some New York courts have permitted advertising claims to be brought under section 349, they have only done so when the complaint alleges that the advertising itself is was a "deceptive practice," such that the claim may fit under section 349. See, e.g. B.S.L. One Owner's Corp. v. Key Intern Mfg., Inc., 640 N.Y.S.2d 135, 136 (App. Div. 1996) ("defendants engaged in *deceptive practices in the advertisement*" of their products) (emphasis added). Further, such false advertising claims have also been brought under section 350, and not 349 alone. Id. See also State v. Middletown Beef Co., 444 N.Y.S.2d 184, 184 (App. Div. 1981). Thus, these cases support Defendant GSK's contention that filing a false advertising claim under 349 alone is not permissible, as it would render section 350 totally superfluous. Accordingly, when, whereas here, a plaintiff pleads false advertising pursuant to only one section of the New York Consumer Protection statute, the allegation necessarily must fall under N.Y. Gen. Bus. Law section 350.

As to Defendant's other objections, we agree that the learned intermediary doctrine also precludes Plaintiff's claim under the consumer protection statute. While the New York courts have yet to confront this specific issue, we believe our holding is entirely consistent with both the statute and the doctrine. This is because the consumer protection statute forbids deceptive acts or practices likely to mislead a reasonable *consumer*, specifically requiring proof that the defendant's acts are directed at consumers, Goshen, 774 N.E.2d at 1196; Oswego, 85 N.Y.2d at 26, while the LID dictates that all pharmaceutical information is directed at *physicians, not consumer-patients*.[33] Applying other state consumer protection statutes, other courts have come to the same logical conclusion that the statute and the doctrine are inherently inconsistent with one another. See, e.g., Heindel, 381 F. Supp. 2d at 384 (applying Pennsylvania law, concluding that the LID bars plaintiff's consumer protection claim). Moreover, we find compelling the argument that Gray is analogous to the facts at hand. While the federal law at issue differs, both securities and prescription drug labeling are highly regulated by the federal government, a fact relied upon by the Gray court. Further, like securities, prescription drugs are not available in the same manner as usual consumer products, also a key component of the Gray court's reasoning.

In sum, even if we did not conclude Hahn barred Plaintiff's non-negligence claims, and that all claims against GSK were dismissed for want of a duty and preemption, the consumer protection portion of Count III would still be dismissed.

c. Infliction of Emotional Distress (Counts V and VI)

[33]We note that the LID is applied with equal force in New York, where it is referred to as the "informed intermediary" doctrine, as in Pennsylvania. Lindsay v. Ortho Pharm. Corp., 637 F.2d 87, 91 (2d Cir. 1980); Krasnopolsky v Warner-Lambert Co., 799 F. Supp. 1342, 1346 (E.D.N.Y. 1992); Martin v Hacker, 628 N.E. 2d 1308, 1311 (N.Y. 1993); Bukowski v. Coopervision, Inc., 185 A.D.2d 31 (N.Y. App. Div. 3d Dep't 1993) (under New York law, all applying the "informed intermediary" doctrine in fixing the scope of liability of manufacturers or sellers for their alleged failure-to-warn of the risks associated with a prescription drug).

Both Defendants next argue that Plaintiff has no right to recover for infliction of emotional distress under either a negligent[34] or intentional theory, because both torts require evidence of immediate proximity to the conduct such that it and its consequences are sensorally observed. (Def. GSK's Mem. at 8-9; Def. Apotex's Mem. at 20-23). The Court agrees.

The tort of intentional infliction of emotional distress ("IIED") is defined as: "extreme and outrageous conduct [that] intentionally or recklessly causes severe emotional distress to another." Hoy v. Angelone, 720 A.2d 745, 753 (Pa. 1998). Where such conduct is directed at a third person, the actor can only be subject to liability for causing emotional distress to a member of such person's immediate family *who is present* at the time. Taylor v. Albert Einstein Med. Ctr., 754 A.2d 650, 653 (Pa. 2000) (emphasis added). Similarly, the Pennsylvania Supreme Court has explicitly held that a showing of the contemporaneous observation of the injury of a close relative is required for a negligent infliction of emotional distress ("NIED") claim. Brooks v. Decker, 516 A.2d 1380, 1382 (Pa. 1986) (father who came upon scene of accident after his son was struck by an automobile failed to state a claim for NIED because he did not witness the accident).

Here, it is undisputed that Plaintiff came upon his wife's body after she had committed suicide. Whatever act or omission was allegedly undertaken by Defendants did not occur in Plaintiff's presence, which is required to establish the tort of infliction of emotion distress under either theory when it involves conduct directed at a third party. Plaintiff argues, however, that the *reasoning* articulated by Pennsylvania courts in requiring presence is that, in the absence of knowledge of the injury beforehand, the third party has no buffer against the full impact of

[34]Although the negligent infliction of emotional distress claim obviously sounds in negligence (the remainder of which such claims are discussed in Part VII.D.2, *infra*), we choose to discuss it with the intentional infliction of emotional distress claim for ease of reference.

observing the scene. Thus, he asserts that so long as the third party contemporaneously observes the *result* of the alleged intentionally outrageous or negligent conduct and has no warning of the incident before coming on the scene, the party sufficiently states a claim for infliction of emotional distress. Since he had no pre-warning of and thus no buffer against the full impact of observing the deceased Mrs. Colacicco after her suicide, Plaintiff therefore asserts both his IIED and NIED claims should survive this motion to dismiss. (Pl's Response to GSK at 14-17; Pl's Response to Apotex at 16-17).

Plaintiff misconstrues the caselaw, which clearly requires presence for both IIED and NIED. Both Mazzagatti v. Everingham, 516 A.2d 672 (Pa. 1986), and Bloom v. DuBois Regional Medical Center, 597 A.2d 671 (Pa. Super. 1991), although cited by Plaintiff, support Defendants' position. In fact, those courts dismissed the NIED counts for failure to plead the element of contemporaneous observance of traumatic infliction of injury by defendants. See Mazzagatti, 516 A.2d at 679 (mother who arrived at scene of accident after daughter was fatally injured by motorist not entitled to recover on theory of NIED); Bloom, 597 A.2d at 682-83 (husband who came upon wife who had attempted suicide at a psychiatric hospital had no cause of action for NIED because he did not witness defendants inflicting harm). Likewise, in Taylor, the parents of a patient who died during a catheterization procedure could not maintain an action for IIED because the mother was not present for the procedure and did not witness the physician's allegedly outrageous conduct. Taylor, 754 A.2d at 653. Accordingly, as with several of the individual claims above, even assuming *arguendo* that Plaintiff's complaint were not otherwise dismissed, the claims for intentional and negligent infliction of emotional distress (Counts V and VI) must still be dismissed.[35]

[35]We also note the independent tort of IIED has never expressly been approved by the Pennsylvania Supreme Court. Taylor, 754 A.2d at 653.

2. Claims Sounding in Negligence

Finally, we consider the individual causes of actions that sound in negligence. As discussed *supra* in Part VII.A.2, we hold that Apotex owed a duty of care to Plaintiff and Plaintiff's decedent, sufficient to give rise to liability against it. Therefore, while barred by preemption, Plaintiff's negligence-based claims against Apotex are unaffected by our conclusions: (1) as to the lack of a duty of care owed to GSK, and (2) as to both Defendants regarding Hahn, which explicitly allows a plaintiff to pursue inadequate warning claims under a theory of negligence. Hahn, 673 A.2d at 891. Therefore, if this Court's conclusion as to preemption were found improper, Apotex would have to respond to each individual claim sounding in negligence.

a. Negligence (Count VII)

Under Pennsylvania law, the elements of negligence are: (1) a duty recognized by law, requiring the actor to conform to a certain standard of conduct for protection of others against unreasonable risks; (2) failure to conform to the standard required; (3) a causal connection between the conduct and resulting injury; and (4) actual loss or damage resulting to interests of another. Griggs v. BIC Corp., 981 F.2d 1429 (3d Cir. 1992) (citing Morena v. South Hills Health Sys., 462 A.2d 680, 684 n.5 (Pa. 1983)).

There is no dispute that Plaintiff has adequately plead the second, third and fourth elements. However, Plaintiff cannot plead negligence without the existence of a duty, which Apotex urges is lacking in this case. (Def. GSK's Mem. at 6-8; Def. Apotex's Mem. at 23-24). However, as we previously held that Apotex owed a duty of care to Plaintiff and Plaintiff's decedent, if preemption did not bar Plaintiff's entire complaint, his negligence claim against Apotex would be adequate to survive this motion to dismiss.

b. Negligence per se (Count VIII)

Defendants also contend that the negligence *per se* claim is impliedly preempted, evidenced by the fact that there is no private right of action under the FDCA. (Def. GSK's Mem. at 9; Def. Apotex's Mem. at 25). See In re Orthopedic Bone Screw Prods. Liability Litig., 159 F.3d 817, 824 (3d Cir. 1998) ("Congress has not created an express or implied private cause of action for violations of the FDCA.").

The doctrine of negligence *per se* liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, a standard of care appropriate to the underlying tort. Thus, if a plaintiff can show violation of a specific statute, this satisfies his or her burden of establishing duty and breach. Here, Plaintiff's negligence *per se* claim is premised on the alleged violation of the FDCA.

As discussed *supra* in Part VI, we hold all Plaintiff's claims, including that for negligence *per se*, are in fact barred by preemption.

c. Negligent Misrepresentation (Count IV)

Finally, Apotex urges that since it made no statements regarding efficacy and safety to the FDA, Plaintiff cannot show the required element of negligent misrepresentation that Apotex knew or should have known that certain representations were false. (Def. Apotex's Mem. at 19-20).

The elements of negligent misrepresentation are as follows: (1) a misrepresentation of a material fact; (2) made under circumstances in which the party ought to have known its falsity; (3) with an intent to induce another to act on it, and; (4) which results in injury to a party acting in justifiable reliance on the misrepresentation. Bortz, 729 A.2d at 561; Gibbs, 647 A.2d at 890.

Accepting as true Plaintiff's averments that material submitted to the FDA and the

labeling itself was intentionally false and misleading to the FDA, the general public, the decedent's physician, and decedent herself, and that decedent and her physician relied on this information, Compl. at 86-91, this claim must survive. Also, it seems to this Court that even if Apotex did not make misrepresentations or material omissions to the FDA when it sought initial approval, Plaintiff's pleadings support the supposition that Apotex was also aware of an increased risk of suicide after approval and did not seek to strengthen its label. Compl. at 87-89. Accordingly, if Plaintiff's complaint were not otherwise dismissed, the Court would decline to dismiss the negligent misrepresentation claim.

d. Strict Liability (Count IX)

As discussed above, Defendants urge that Hahn holds that a manufacturer of drugs is not strictly liable for injury in connection with the use of prescription drugs. (Def. GSK's Mem. at 9-10; Def. GSK's Reply at 9). We need not re-visit Plaintiff's argument that Hahn does not apply at length; it suffices to say that as discussed *supra* in Part VII.C, we hold that Hahn clearly bars strict product liability claims against drug manufacturers, as well as any other failure-to-warn claim that does not sound in negligence. Hahn, 673 A.2d at 890.[36]

VIII. Conclusion

For the foregoing reasons, Defendants' Motions to Dismiss (Doc. Nos. 5 and 10) will be granted. An appropriate Order follows.

[36]Even Plaintiff concedes that, on its face, Hahn appears to preclude his strict liability claim. (Pl's Supp. Mem. at 4).

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

JOSEPH C. COLACICCO, Plaintiff,	:	CIVIL ACTION
v.	:	
APOTEX, INC., et al. Defendants	:	NO. 05-5500

ORDER

AND NOW, this day of May 2006, based on the foregoing memorandum and upon consideration of the pleadings and briefs, it is hereby ORDERED that:

1. Defendants' Motions to Dismiss (Nos. 5 and 10) will be GRANTED WITH PREJUDICE.

2. The Clerk shall close this case.

BY THE COURT:

/s/ Michael M. Baylson

MICHAEL M. BAYLSON, U.S.D.J.